

Addendum



LEGAL NOTES

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL
BEFORE ATTEMPTING TO OPERATE INSTRUMENT.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

- | | | |
|------------------|---|---------------------------------------|
| WARNING | - | Might cause injury. |
| CAUTION | - | Might cause damage to the instrument. |
| IMPORTANT | - | Might cause misleading results. |

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
 - You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
 - You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.
-

Beckman Coulter, Inc. urges its customers to comply with all national health and safety standards such as the use of barrier protection. This may include, but it is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

WARNING Risk of operator injury if all covers are not secured in place prior to instrument operation or you attempt to replace a part without carefully reading the replacement instructions. Do not attempt to replace any component until you carefully read the instructions for replacing the component.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

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This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

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DOCUMENT OVERVIEW

Online Help and this Addendum

This addendum explains the operational changes in software version 2C for your COULTER GEN•S™ System. This addendum cannot be used with previous versions of GEN•S System manuals. The information in this addendum is included in the GEN•S System Online Help. The GEN•S System Online Help contains,

- all of the information in this addendum
- all of the information contained in each of the GEN•S System manuals
- popup help information that is not contained in the GEN•S System manuals
- a Readme file, accessed from  on the help window, that contains a description of the changes in GEN•S 2B1 software and GEN•S 2C software.

The following GEN•S System manuals are affected by this addendum.

- COULTER GEN•S System Reference Manual, PN 4237221B
- COULTER GEN•S System Operator's Guide, PN 4237222B
- COULTER GEN•S System Special Procedures and Troubleshooting Manual, PN 4237223D
- COULTER GEN•S SM™ SlideMaker Operator's Guide, PN 4237212A

Keep this addendum with your set of GEN•S System manuals.

Previous Versions of this Addendum

Discard previous versions of this addendum. The information in previous versions of this addendum has been incorporated in the GEN•S System manuals listed above.

How to Use This Addendum



A label icon  appears throughout this document next to information that has changed or is new for the 2C software release. Update labels are supplied with this document. Detailed instructions on how to place the update labels appear at the end of this document.



Place an update label next to heading 7.4, Adding A Sample Request To The ToDo List on page 7-7 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

ADDING A SAMPLE REQUEST TO THE ToDo LIST

1. Select  on the Command Center to display the Patient Tests application.
2. Select . The Add Test window appears with blank fields.
3. If you want to add a test or sample request:
 - a. Select the specific test identifiers you want to add.
 - b. Provide the sample identification information for the tests. Use  to move between fields.
 - c. Specify the demographic information.

IMPORTANT Risk of incorrect identification. Before saving identification information, check that you typed the information properly.

4. Select:



To save the test information and clear the fields on the window so you can add another test.



To save the test information after the final entry.



Place an update label next to heading Adding A Test To An Existing Set Of Sample Results onpage 7-8 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

ADDING A TEST TO AN EXISTING SET OF SAMPLE RESULTS

1. Select  on the Command Center to display the Patient Tests application.
2. Find the results you want to add a test to.
3. Select . The Edit Sample window appears.
4. Select the specific test identifiers you want to add or remove.
5. Provide the sample identification information for the tests. Use the tab key to navigate between fields.

IMPORTANT Risk of incorrect identification. Before saving identification information, check that you typed the information properly.



6. Select to save the test information.

Reports with Pending status include a special message indicating the status. When all tests complete processing, the report includes a special message that indicates the change in status.



Place an update label next to heading **Turning Autostop Off/On** on page 8-3 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

AFTER # RUNS

The After # Runs field appears next to No Match, No Read or Partial Aspiration. This field is gray and inactive unless AutoStop is enabled for its corresponding Sample Status Message. For example, if AutoStop is enabled for Partial Aspiration and disabled for No Match and No Read, then the After # Runs field will be available next to Partial Aspiration only.

A value from 1 to 10 may be entered next to the specific Run Status Message that is enabled. This number indicates the number of consecutive specific Run Status Messages that must occur before AutoStop is triggered. For example, if three is entered in the After # Run Field next to the Partial Aspiration, an AutoStop condition will be triggered when three consecutive Partial Aspiration messages occur.



Place an update label next to heading ?? on page ?? of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

ARCHIVE FILENAME FIELD

Type an 8-character filename followed by a period and a 3-character extension.

For control information, the Workstation prefills this field with the lot number of the first control you selected to archive. The Workstation automatically adds .CSV to the end of the filename when you archive the information.

For patient information, the Workstation prefills this field with the letter P, the year, month, and day (Pyyyymmdd). The Workstation automatically adds .CSV to the end of the filename when you archive the information.

The file can be retrieved into any spreadsheet application. Use your spreadsheet program's instructions to transpose the information if it is not in a readable format.



Place an update label next to heading **Turning Autostop Off/On** on page 8-3 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

AUTO STOP



Auto Stop indicates that you want the instrument to stop when it comes across a control result for the specified lot number that appears outside the expected range.

Note:  Controls in AutoStop Criteria must be selected on the System Run Configuration window in order to activate the Auto Stop function.

Deselect this item to ensure the instrument continues processing when it comes across a control value outside the expected range.

Changing this option does not affect any previously run controls; only subsequent control runs.



Place an update label next to **Turning Autonumbering Off/On** on page 8-33 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

AUTONUMBERING & STARTING AT FIELDS

These fields appear gray and inactive unless Cass/Pos is specified as the positive identifier. AutoNumbering is an instrument-specific option.

1. Select  if you want the Workstation to automatically increment an accession number for samples received from the selected instrument. This activates the Starting At field.
2. Select  to display the Starting At dialog box.
3. Type the first six-digit number you want used for the AutoNumbering option. If necessary, the Workstation pads the number with leading zeros.

4. Select .

The next sample received from the instrument, regardless of the test type, appears with this number in the Sample ID field. The number appears with an N flag indicating the Workstation assigned it using the AutoNumbering option. Each subsequent sample receives the next number in ascending order. When the Workstation reaches 999999, it restarts the number at 000000.

Deselect this field to ensure the Workstation does not use an accession number.



Place an update label next to heading 8.11, **Setting Up Rules for Flagging Sample Results** on page 8-15 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

AUTOVALIDATION OVERVIEW

The enhanced Autovalidation procedure provides information as to the state of the sample. The sample can have one of three states with respect to validation: AutoValidated, meaning that it has passed all criteria for validation; Validated, meaning that although it failed at least one criteria, the operator has manually validated the sample; Not Validated, meaning that the sample failed at least one criteria and has not been manually validated.

On the screen, samples which are AutoValidated will not appear in the Reflex, Delta, or Review folders, and will not have the Validate button enabled. If the sample fails validation for non-decision rule criteria, it would appear in the Review Folder. If the sample fails for Decision Rule criteria, it could appear in either the Delta Check or Reflex folders (depending which one was triggered), or in the Review folder, depending whether they have configured Delta Check and Reflex failures to go to the Review folder. It is possible, if the sample fails both decision rule-related and non-rule related criteria, for the sample to appear in both or all three folders. If the user reviews and manually validates the sample, it would no longer appear in any of these folders, and the validate button would be in a depressed state when that single sample is selected.

For the print and host transmission, these messages are output as "Sample AutoValidated", "Sample Not Validated", or "Sample Validated". In addition, individual codes will provide validation information for predefined parameter sets, referred to as parameter blocks. If at least one parameter from the parameter block is included in the reported results, the appropriate validation code will be displayed. The codes may be disabled for host transmission in the Host Communications Setup area.

The major difference between the screen and print is that the screen is not profile specific. This means that on screen, all parameters, suspect/definitive messages, and rules triggered will be displayed, and the validation status depends on the whole sample. For the print and host transmission, only those parameters, suspect/definitive messages, and rule messages which are part of the profile are output, and the validation codes and messages are based on this output.

The logic for arriving at the validation status is as follows:

We first reduce the parameters to an active set. The set of active parameters starts with the set of parameters which is enabled for the system in parameter setup. It is further reduced to those parameters which were either run on the analyzer or edited into the sample. For printing and transmission, the active set is further reduced to the parameters included in the selected profile. If the status we are looking for is a validation code, the active set is further reduced to the parameters applicable to that code.

Active Set: For Flagging Limits, Decision Rules and AutoValidation logic, the Active Set of parameters are defined as those parameters that,

- are enabled for the System (System Setup – Patient – Parameters window),
- are enabled for the Report Profile you are using (System Setup – Patient –Reporting Options window),

- are part of the Test Mode you are running (C, CD, CDR, CR, or R on the Analyzer Screen) or have been edited into the sample,
- are included in the parameter block of the validation code you are looking for.

For example, suppose that all parameters are enabled for the system except research. Now suppose that a CR sample is run. We are now only looking at CR parameters, except the research ones. Now if we are looking at the printout and the selected profile is CBC, we are reduced to only the CBC parameters. To determine the status of the Validation Message we are looking for all the CBC parameters. To determine the status of the parameter codes, such as the C Code (CBC parameter block), then we're still looking at all CBC parameters. If it is H Code, we're looking at only Hgb and Hct parameters. The W code only looks at the WBC, Hgb and Plt parameters. If we're looking for the D code (Diff parameter block) or R code (Reticulocyte block), we have no parameters, and the code would not be displayed.

Now that we know which parameters to include, we will look for anything which causes an AutoValidation failure:

- Any active parameter which exceeds limits, where the limit has been configured as autoverification criteria. This could also be based on a definitive message, where the definitive set has been specified as autoverification criteria.
- H & H Check Failed is a separate check. Since it is not tied to any limit set, it can not be configured as autoverification criteria. It will always trigger a failure when both HGB and HCT are part of the active set.
- Any active parameter which has a nonnumeric value (+++++, :::::, ..., -----), a Review flag, Partial Aspiration (P), exceeds linearity (+), WBC backlight flag (*), or MCV exceeds threshold (*).
- Any suspect (non-research) flag, where the active parameter set includes at least one parameter from the suspect message parameter group. Suspect messages are associated with either CBC, Diff, or Retic parameters. If, for example, a CBC suspect message is triggered and at least one CBC parameter is in the active set, we have an autovalidation failure.
- Any reflex or delta rule, where ALL parameters included in the rule must be in the active set.

IMPORTANT Several precautions have been taken to ensure integrity of Manual Validation. If new data is collated to a sample, if the sample is edited in a way that would cause a reflag, or if the profile is changed, manual validation for the sample is cleared.

Autovalidation Example

Autovalidation Setup

- Enable Validation Codes
- Enable AutoVerification Criteria for Action Limits
- Enable Decision rules = Reflex rule is defined as "If Retic % < 0.2 then Make Retic Smear and scan slide."

Sample Setup:

- Test Mode = CBC/Diff

- Patient Sample preassigned with a CBC and Retic Report Profile

Sample Results: (printed and transmitted)

Comments: Make Retic Smear and scan slide

WBC	4.8 10 ³ /L	RBC	2.53 10 ⁶ /L	Plt	80 aL 10 ³ /L
		Hgb	6.3 g/dL	MPV	10.3 fL
		Hct	19.6 %		
		MCV	77.4 fL		
		MCH	24.9 pg		
		MCHC	32.1 g/dL		
		RDW	16.1 %		
		Ret %	%		
		Ret #	/pL		

End of Completed Report, Sample Not Validated, C NV, H AV, W NV

Manual Validation:

Once the results are reviewed and manually validated at the workstation the report appears as follows.

Comments:

WBC	4.8 10 ³ /L	RBC	2.53 10 ⁶ /L	Plt	80 aL 10 ³ /L
		Hgb	6.3 g/dL	MPV	10.3 fL
		Hct	19.6 %		
		MCV	77.4 fL		
		MCH	24.9 pg		
		MCHC	32.1 g/dL		
		RDW	16.1 %		
		Ret %	%		
		Ret #	/pL		

End of Completed Report, Sample Validated, C V, H AV, W V

Sample Setup:

Run the sample in the Retic mode, sample results are as follows.

Comments: Make Retic Smear and scan slide

WBC	4.8 10 ³ /L	RBC	2.53 10 ⁶ /L	Plt	80 aL 10 ³ /L
		Hgb	6.3 g/dL	MPV	10.3 fL
		Hct	19.6 %		
		MCV	77.4 fL		
		MCH	24.9 pg		
		MCHC	32.1 g/dL		
		RDW	16.1 %		
		Ret %	0.14 %		
		Ret #	.0035 /pL		

End of Completed Report, Sample Not Validated, C NV, H AV, W NV, R NV



Place an update label next to step 10 on page 8-12 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

AUTOVERIFICATION CRITERIA



indicates that you want any results that exceed the values in this limit name placed into the Review Folder. The results of the sample will continue to be printed and transmitted according to the run configuration setup, however, a "Sample Not Validated" message appears with the results.

Deselect this field to ensure the results are not placed in the Review Folder.



Place an update label next to heading **Changing Your Password** on page 8-22 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

CHANGING YOUR PASSWORD

1. Select  on the Command Center to display the System Setup window.
2. Select  to display the Change Password window.
3. Type your current password and press .

4. Type your new password and press .
 5. Type your new password a second time for verification.
 6. Select  to save the new password and close the window.
- If you want a blank password, perform the procedure above except,

- Step 4, type your new password then use the backspace key to erase the password and press .
- Step 5, type your new password a second time then use the backspace key to erase the password.

After you select  to save the new password and close the window, you will be able to log on without using a password.



Place an update label next to heading **Checking Daily Test Results** on page 2-3 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

CHECKING DAILY TEST RESULTS

1. Select  on the Command Center to display the Quality Assurance application.
2. If necessary, select  to display the daily startup test results.
3. If you want to see past startup test results:
 - a. Select .
 - b. Select a row indicating the date, time and type of test results you want to see. The results appear on the window.
 - c. **Note:** Select only 1 row. Daily Checks results will not be displayed if you select more than 1 row of results.
4. If necessary, select the instrument to check.
5. Check the reagent status, background status and subsystem status for any items that failed.
6. Select  to see startup test details. You can also select  to see background test results on the QA Results & Graphics window.
7. Take appropriate action to resolve any failed items.



Place an update label next to heading **Turning Autostop Off/On** on page 8-3 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

CONTROLS FIELD



indicates that the selected instrument stops if it comes across a control that is out of limits or expired and the control was set up as an AutoStop control. An expired control or non-numeric control results, such as voteouts and partial aspirations, will cause an AutoStop if enabled.



Note: Auto Stop must be selected on the controls setup window in order to activate the Auto Stop function.

Deselect this field to ensure the instrument continues processing when a control is out of limits, regardless of how the AutoStop option was specified when the control was set up.



Place an update label next to heading **Cycling Controls In Automatic Aspiration Mode** on page 3-4 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

CYCLING CONTROLS IN AUTOMATIC ASPIRATION MODE

1. Ensure the instrument is set up for the appropriate control.
2. Prepare the controls according to the directions in the package insert.
3. Ensure the controls are properly set up on the Workstation.

Note: If you run a Coulter control without setting it up, the Workstation automatically creates control setup information for you. The control information identifies the lot number, source, type and level of the control.

4. Load the cassette with the control material.
5. Place the cassette firmly and securely into the loading bay. The instrument begins to cycle the controls.
6. On the Command Center, select **AUTO ANALYSIS** as the processing control if your control tubes have bar-code labels. See processing control if you run controls without bar-code labels.
7. Review the control results.



Place an update label next to heading **Cycling Controls In Manual Aspiration Mode** on page 3-5 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

CYCLING CONTROLS IN MANUAL ASPIRATION MODE

1. Ensure the instrument is set up for the appropriate control.
2. Prepare the controls according to the directions in the package insert.
3. Ensure the controls are properly set up on the Workstation.

4. Go to the Diluter Keypad.
5. Press .
6. Press .
7. Use the Keypad or the handheld scanner to provide the lot number of the control tube.
8. Press .
9. Remove the stopper from the tube.
10. Immerse the aspirator tip in the tube. The instrument automatically aspirates the control.

Tip: When using Manual aspiration mode, the instrument automatically aspirates the sample. If the instrument fails to aspirate the sample, the optical sensors on the activator may be malfunctioning.

Press the black activator that surrounds the aspirator tip to aspirate the sample, and call your Coulter Representative.
11. When you hear a beep, remove the tube from the aspirator tip. The probe cleaner retracts the aspirator and automatically cleans it.
12. At the Workstation, review the results from the control.
13. On the Command Center, select **AUTO ANALYSIS** as the processing control.



Place an update label next to heading 7.1, **Database & ToDo Window** on page 7-1 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

DATABASE & ToDo TREE LIST

Double-click This



Completed



To Do



Explorer



Review List



Delta Checks

To See This

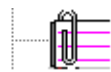
A list of the test groups for completed sample runs. Select a test group to see all the records that contain completed sample runs for the specific test type.

A list of the test groups for pending sample test requests. Select a test group to see all the records that contain pending test requests for the specific test type.

A list of the results from the last time you used the DataBase Explorer window.

A list of the results posted to the Review List based on your flagging (AutoVerification) and decision criteria setup. Manually validated samples will not appear.

A list of the results posted to the Delta Check List based on your decision criteria for delta check setup. Manually validated samples will not appear.



Reflex Manager

A list of the results posted to the Reflex Manager List based on your decision criteria for reflex manager setup. Manually validated samples will not appear.



Save List

A list of all the results that have been saved (marked with  for later retrieval in the database.



Slide List

A list of all the results that contain slide requests appears as a sub-folder in both the Completed and ToDo folders. The Completed Slide List contains all samples for which a slide has been made. The ToDo Slide List contains all samples for which not all requested slides have been made (sample could be pending or completed).



Place an update label next to heading **7.1, Database & ToDo Window** on page 7-1 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

DATABASE NAVIGATION BUTTONS

These buttons enable you to move sequentially through the database folder selected in the Navigation field. Initially, the list is sorted by the date and time of sample analysis—the most recent sample results appear at the top of the list.

Note: If your Workstation is connected to more than one instrument the database displays results from all the instruments, not just the instrument selected on the Command Center.

Select This

To Display The



The first sample that appears on the list, which is the most recent sample in the database.



First sample that follows the currently displayed sample



First sample that precedes the currently displayed sample result



Last sample in the list, which is the oldest sample in the database.

Menu Access:

Sample » First Patient

Sample » Previous Patient

Sample » Next Patient

Sample » Last Patient



Place an update label next to heading **Defining Reflex Manager Criteria** on page 8-16 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

DEFINING REFLEX MANAGER CRITERIA

Note: To perform this task, you must first perform steps 1 through 8 of setting up rules for flagging limits.

1. Specify an item you want to check.

IMPORTANT REVIEW YOUR DECISION RULES THAT CONTAIN MULTIPLE PARAMETERS. If you create a rule that has more than one parameter or contains more than one item that is related to a parameter, all of the parameters included in the rule (even if an OR condition is used) must also be included in the parameters reported in your report profile. Refer to Example A.

2. If you selected a parameter:
 - a. Select the operator you want used for the criterion.
 - b. Specify the value you want used for the criterion.
3. If you want more than one condition included in this criterion, specify the logical operator you want to use.
4. If you want more than one condition included in this criterion, repeat steps 1 through 3 up to two times.
5. Specify the rule action you want used.
6. Select  to save the criterion with the criterion name you specified.



Place an update label next to heading **Deleting Patient Data** on page 7-3 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

DELETE PATIENT SAMPLE

When this button appears in conjunction with a list or table, it appears gray and inactive until you select one or more items in the list or table.



Select  to display the Patient Data - DELETION REQUESTED window where you can verify the item you want deleted.

If you select this button, the Workstation deletes all the sample information. You can no longer retrieve the information from the database.

Note: The demographic information (patient record) is not deleted from the database unless the GEN•S Workstation software is restarted and there are no other sample records in the database associated with that patient record.

Required Access Level: Advanced Operator or Lab Administrator.

Menu Access: **Sample ► Delete Sample**



Place an update label next to step 10 on page 8-15 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

DETAILED DESCRIPTION OF RULE FIELD

This field displays the details of your rule. The Workstation automatically inserts the following elements to help you understand the rule as you create it. The Physician, Location and Make Slide selections in your rule will not be displayed in the Detailed Description of Rule field. They are displayed on the Decision Rules & Criteria table.

This Appears

[Reflex] IF

[Delta Check] IF

[Suspect]

[Definitive]

[THEN]

When

Defining a Reflex Manager rule.

Defining a Delta Check rule.

Selecting any suspect message.

Selecting any definitive message.

Selecting a rule action.



Place an update label next to 8.10, **Setting Up Flagging Limits** on page 8-12 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

DIFF FLAG PREFERENCES

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

On this screen you can adjust flagging sensitivity at three levels for these differential flags,

- Blast
- Variant Lymph
- NRBC
- Imm NE 1
- Imm NE 2

A checkbox labelled REPORT is defaulted to ON for Imm NE 1. If REPORT is deselected, then Imm NE 1 reporting is disabled (OFF).

The Diff Flagging configuration selected is recorded in the Algorithm Revision number which is printed on GEN•S, STKS, and MAXM report printouts.

1. Select  on the Command Center to display the System Setup window.
2. Select  to display the Patient Setup window.
3. Select **Diff. Flag Preferences** to display the Diff Flag Preferences window.
4. Click on a slider bar and move it up or down.

Lower flagging rates are selected by moving the slider near the bottom of the control. The down arrow indicates lower flagging rates. Higher flagging rates are selected by moving the slider near the top of the control. The up arrow indicates higher flagging. The slider will not travel fully to the top or bottom of the control.



Place an update label next to heading 5.1, **Reviewing Sample Results** on page 5-1 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

DRAWN DATE

Description

The date and time the sample was drawn from the patient. The date format for drawn date is the same date format set up for your laboratory.

Editing

You can edit this field on the Edit Sample window. Type the date and time the sample was drawn from the patient in the format set up for your laboratory.

Note: time is not a mandatory field.



Place an update label next to steep 5 on page 8-19 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

ENABLE VALIDATION

☒ indicates the Workstation includes the new AutoValidation codes with the standard data set transmitted to your information system.



Place an update label next to heading 5.8, **Flags And Codes** on page 5-11 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

FLAGS AND CODES

IMPORTANT Flagging is evaluated when the sample is analyzed. Flagging is reevaluated for a sample when the results are manually edited, or when new results are received for a pending sample. Flagging is not reevaluated upon a change of flagging limits for results already in the database.

IMPORTANT Coulter suggests using all available flagging options to optimize the sensitivity of instrument results. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

 (yellow) Indicates reference interval low or high.

 (red) Indicates an action, critical or other flag.

Flags appear to the right of the result. Codes appear in place of results when the system cannot obtain results. When looking at codes and flags, look for patterns. For example, see if all results show the same or related codes. If they do not, look at all the RBC parameters, then the WBC parameters. For specific parameters, the flagging occurs as a result of the flagging on other parameters.

Flags

- *** Result exceeds instrument's counting threshold. Follow your laboratory's policies for reviewing the sample. This flag is applicable to WBC and MCV only.
- +** Result exceeds linearity (reportable) range. Follow your laboratory's policies for reviewing the sample.
- aL** Result is lower than your action low limits. Follow your laboratory's policies for reviewing the sample.
- aH** Result is higher than your action high limits. Follow your laboratory's policies for reviewing the sample.
- cL** Result is lower than your critical low limits. It is a critical value and requires immediate attention. Follow your laboratory's policies for reviewing the sample.
- cH** Result is higher than your critical high limits. It is a critical value and requires immediate attention. Follow your laboratory's policies for reviewing the sample.
- D** Result triggered a Delta Check rule as defined by your laboratory.
- e** Result has been calculated from a manually edited parameter. This flag overwrites +, *, and R flags.
- E** Result has been edited. This flag overwrites +, *, and R flags.
- H** Result is higher than your default reference interval high limit. Follow your laboratory's policies for reviewing the sample.
- L** Result is lower than your default reference interval low limit. Follow your laboratory's policies for reviewing the sample.
- P** The instrument detected a partial aspiration during sample analysis or the blood detectors are disabled.
- R** Review the result according to your laboratory's protocol. When editing parameter results, this flag requires special handling. Any parameter derived from an R-flagged parameter cannot be recalculated until the parameters with the R flags have been edited. R flags may also indicate a system alarm has occurred. System alarms may also indicate a flow cell error. Check the message line and the event log for details.

You may want to look at the messages that appear on the Research Data window. The Research Data window provides more detailed research data.

Codes

IMPORTANT Incorrect results can occur. If the WBC, RBC, HGB, or PLT have +++++ when cycling in Manual mode, run a blank cycle before analyzing the next test sample to prevent carryover to the next sample. When cycling in Automatic mode, rerun the sample immediately following the one with the +++++. Sample dilutions may also result in wrong differential results. When WBC is overrange, if you dilute the sample to rerun it, ensure you set the instrument to CBC mode before you cycle the diluted sample.

- Incomplete computation. This could occur on calculated parameters because of a voteout (- - - - -) or overrange results (+++++) for the parameters used in the calculation. Check other parameters, such as WBC, to ensure sufficient data was received for calculations.
- - - - - When this code appears for CBC parameter results and no average histogram appears for the affected parameter, it indicates a total voteout.

If this code appears for WBC, the WBC differential absolute number parameter results appear as since they are calculated from the white count and the WBC result was non-numeric.
- +++++ This result exceeds the instrument's operating range. Follow your laboratory's policies for reviewing the sample
- ::::: The instrument detected a clog in the flow cell. PC1, PC2 or FC will be displayed on the y-axis of the dataplot



Place an update label next to heading 8.12 **Setting Up Reports** on page 8-17 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

GEN•S report format—chartable report

Algorithm Revision Numbers

A value is printed below the Institution Name that indicates the revision of the differential and reticulocyte algorithm installed. The release is indicated as D:X.X [00000] R:X.X. The values in brackets indicate the Differential Preference selections made by Lab Administration. Differential Preference selections are the low level (1), mid level (2) or high level (3).

Report Comments

Decision Rules & Criteria messages appear in the comment area.

Printed Report Footer

Any or all of the following footers can appear when you print a report:

This footer	Means This
End of completed report	The sample was not preassigned in the ToDo list or all the test requests for the sample are completed.



Place an update label next to heading **8.12 Setting Up Reports** on page 8-17 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

GEN•S REPORT FORMAT—IN-LAB REPORT

Algorithm Revision Numbers

A value is printed below the Institution Name that indicates the revision of the differential and reticulocyte algorithm installed. The release is indicated as D:X.X [00000] R:X.X. The values in brackets indicate the Differential Preference selections made by Lab Administration. Differential Preference selections are the low level (1), mid level (2) or high level (3).

Report Comments

Decision Rules & Criteria messages appear in the comment area.

Printed Report Footer

Any or all of the following footers can appear when you print a report:

This footer	Means This
End of completed report	The sample was not preassigned in the ToDo list or all the test requests for the sample are completed.
End of preliminary report	At least one test request for the sample is pending.
End of additional tests report	After the sample was run and printed with an End of completed report footer, an additional test was requested and run.
Blood Detector OFF	The sample was run with the blood detector disabled.
SYSTEM ALARM	A system alarm occurred when this sample was run.
Validation Messages	System reports Sample Validated, Sample Not Validated or AutoValidated.

2/4/99 15:55:23 Page 1 of 1 SER		Coulter Technology Center D:\0.0\132311 (P/N) 526-6932		Coulter Corporation P. O. Box 269015 Miami, FL 33116-9015	
---------------------------------------	--	--	--	---	--

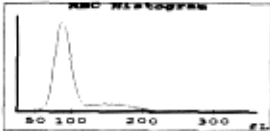
CD	A	Case / Pos	Sample ID	Date	Time	Run Status	Instrument	Operator
		003611	-----	1/28/99	16:06:23	Completed	Z37010	SER

Patient ID Gender Location Physician Date of Birth Comments:	Last Name Seq # Age	First Name Drawn Date User Field 1 User Field 2 User Field 3
---	---------------------------	--

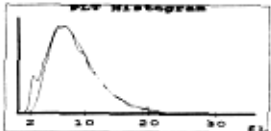
Report Name	All Parameters	Last Modified:	02/04/99	By:	SER
WBC	5.7	10 ³ /μL	RBC	4.38	10 ⁶ /μL
NE %	58.5	%	HGB	13.2	L g/dL
LY %	28.9	%	HCT	39.8	%
MO %	10.1	%	MCV	90.6	fL
EO %	2.2	%	MCH	30.2	pg
BA %	0.3	%	MCHC	33.2	g/dL
NE #	3.4	10 ³ /μL	RDW	13.3	%
LY #	1.7	10 ³ /μL			
MO #	0.6	10 ³ /μL	RET %		
EO #	0.1	10 ³ /μL	RET #		
BA #	0.0	10 ³ /μL			

PLT 287 MPV 8.9	10 ³ /μL fL	CD4 % CD8 % CD4 # CD8 # CD4:8
--------------------	---------------------------	---

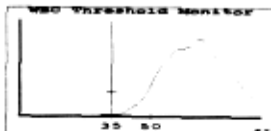
Suspect/Definitive Messages:



RBC Histogram



PLT Histogram



WBC Threshold Monitor



WBC



Empty



Empty



Empty

End of Completed Report, Sample Auto Validated, C AV, D AV, H AV, W AV / 01B1S93B



Place an update label next to heading 8.12 **Setting Up Reports** on page 8-17 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

MAXM-LIKE REPORT FORMAT

Note: MAXM A and MAXM B report formats have different header styles and MAXM B format is slightly larger.

Retic Dataplot

The retic dataplot selection is not available on MAXM A or MAXM B report formats.

Algorithm Revision Numbers

A value is printed below the Institution Name that indicates the revision of the differential and reticulocyte algorithm installed. The release is indicated as D:X.X [00000] R:X.X. The values in brackets indicate the Differential Preference selections made by Lab Administration. Differential Preference selections are the low level (1), mid level (2) or high level (3).

Report Comments

Decision Rules & Criteria messages appear in the comment area.

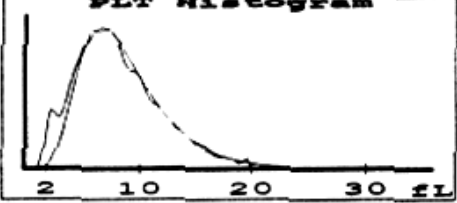
Printed Report Footer

Any or all of the following footers can appear when you print a report:

This footer	Means This
End of completed report	The sample was not preassigned in the ToDo list or all the test requests for the sample are completed.
End of preliminary report	At least one test request for the sample is pending.
End of additional tests report	After the sample was run and printed with an End of completed report footer, an additional test was requested and run.
Blood Detector disabled	The sample was run with the blood detector disabled.
SYSTEM ALARM	A system alarm occurred when this sample was run.

2/4/99 15:56:19 Coulter Technology Center
Page 1 of 1 D:10.0[13231]
SER (800) 526-6932



Sample ID	WBC	5.7		RBC	4.38	
-----		%	#	HGB	13.2	L
Patient ID	NE	58.5	3.4	HCT	39.8	
	LY	28.9	1.7	MCV	90.6	
Seq #	MO	10.1	0.6	MCH	30.2	
Date 1/28/99	EO	2.2	0.1	MCHC	33.2	
Time 16:06:23	BA	0.3	0.0	RDW	13.3	
Case / Pos 003611		%	#			
	RET					
Last Name						
				PLT	287	
First Name	CD4			MPV	8.9	
	CD8					
	CD4:8					

Suspect/Definitive Messages:

End of Completed Report, Sample Auto Validated, C AV, D AV, H AV, W AV / 01B1S93B



Place an update label next to heading Turning Autostop Off/On on page 8-3 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

NO MATCH

☒ indicates that the selected instrument stops after it receives the number of consecutive NO MATCH messages displayed in the After # Runs field.

Deselect this field to ensure the instrument continues to process samples when it receives NO MATCH messages.



Place an update label next to heading **Turning Autostop Off/On** on page 8-3 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

NO READ



indicates that the selected instrument stops after it receives the number of consecutive NO READ messages displayed in the After # Runs field.

This AutoStop cannot be disabled.



Place an update label next to heading **8.12 Setting Up Reports** on page 8-17 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

ONYX-LIKE REPORT FORMAT--CHARTABLE REPORT

Algorithm Revision Numbers

A value is printed below the Institution Name that indicates the revision of the differential and reticulocyte algorithm installed. The release is indicated as D:X.X [00000] R:X.X. The values in brackets indicate the Differential Preference selections made by Lab Administration. Differential Preference selections are the low level (1), mid level (2) or high level (3).

Report Comments

Decision Rules & Criteria messages appear in the comment area.

Printed Report Footer

Any or all of the following footers can appear when you print a report:

This footer	Means This
End of completed report	The sample was not preassigned in the ToDo list or all the test requests for the sample are completed.
End of preliminary report	At least one test request for the sample is pending.
End of additional tests report	After the sample was run and printed with an End of completed report footer, an additional test was requested and run.
Blood Detector OFF	The sample was run with the blood detector disabled.
SYSTEM ALARM	A system alarm occurred when this sample was run.
Validation Messages	System reports Sample Validated, Sample Not Validated or AutoValidated.

Patient ID: _____ Name: _____ Operator ID: SER
 Drawn Date: _____ Seq #: _____
 Location: _____ Physician: _____ Gender: _____
 Date of Birth: _____ Age: _____
 Comments: _____

CD	A	Cass / Pos	Sample ID	Date	Time	Run Status	Instrument	Operator
		003611	-----	1/28/99	16:06:23	Completed	Z37010	SER
WBC	5.7		10 ³ /μL	RBC	4.38	10 ⁶ /μL	PLT	287
				HGB	13.2	L g/dL	MPV	8.9
NE %	58.5	%		HCT	39.8	%		
LY %	28.9	%		MCV	90.6	fL	CD4 %	
MO %	10.1	%		MCH	30.2	pg	CD8 %	
EO %	2.2	%		MCHC	33.2	g/dL	CD4 #	
BA %	0.3	%		RDW	13.3	%	CD8 #	
NE #	3.4		10 ³ /μL				CD4:8	
LY #	1.7		10 ³ /μL	RET %				
MO #	0.6		10 ³ /μL	RET #				
EO #	0.1		10 ³ /μL					
BA #	0.0		10 ³ /μL					

CD	A	Cass / Pos	Sample ID	Date	Time	Run Status	Instrument	Operator
		003611	-----	1/28/99	16:06:23	Completed	Z37010	SER

Microscopic Examination

Morphology Comments

Blast		Neutrophil	
Promyelocyte		Lymphocyte	
Myelocyte		Monocyte	
Metamyelocyte		Eosinophil	
Band		Basophil	
Prolymphocyte		NRBC	
Promonocyte		Other	

Comments:

End of Completed Report, Sample Auto Validated, C AV, D AV, E AV, W AV / 01B1S93B

CD	A	Cass / Pos	Sample ID	Date	Time	Run Status	Instrument	Operator	
		003611	-----	1/28/99	16:06:23	Completed	Z37010	SER	
Reference Intervals				Limit Set Name: Adult		Last Modified: 11/4/98			
						By: SER			
				Low	High		Low	High	
WBC	4.3	10.0	10 ³ /μL	RBC	4.38	5.77	10 ⁶ /μL	PLT	156
				HGB	13.6	17.2	g/dL		400
NE %	41.0	73.0	%	HCT	39.5	50.3	%	MPV	6.8
LY %	19.4	44.9	%	MCV	80.7	95.5	fL		10.8
MO %	5.1	10.9	%	MCH	27.2	33.5	pg	CD4 %	100.0
EO %	0.9	6.0	%	MCHC	32.7	35.6	g/dL	CD8 %	100.0
BA %	0.3	1.5	%	RDW	11.8	14.3	%	CD4 #	
NE #	2.1	6.1	10 ³ /μL					CD8 #	
LY #	1.3	3.5	10 ³ /μL					CD4:8	
MO #	0.3	0.9	10 ³ /μL	RET %	0.52	3.53	%		
EO #	0.0	0.5	10 ³ /μL	RET #	.0200	.1600	10 ⁶ /μL		
BA #		0.2	10 ³ /μL						



Place an update label next to heading **8.12 Setting Up Reports** on page 8-17 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

ONYX-LIKE REPORT FORMAT-IN LAB REPORT

Algorithm Revision Numbers

A value is printed below the Institution Name that indicates the revision of the differential and reticulocyte algorithm installed. The release is indicated as D:X.X [00000] R:X.X. The values in brackets indicate the Differential Preference selections made by Lab Administration. Differential Preference selections are the low level (1), mid level (2) or high level (3).

Report Comments

Decision Rules & Criteria messages appear in the comment area.

Printed Report Footer

Any or all of the following footers can appear when you print a report:

This footer	Means This
End of completed report	The sample was not preassigned in the ToDo list or all the test requests for the sample are completed.
End of preliminary report	At least one test request for the sample is pending.
End of additional tests report	After the sample was run and printed with an End of completed report footer, an additional test was requested and run.
Blood Detector disabled	The sample was run with the blood detector disabled.
SYSTEM ALARM	A system alarm occurred when this sample was run.



Place an update label next to heading **Turning Autostop Off/On** on page 8-3 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

PARTIAL ASPIRATION



indicates that the selected instrument stops after it receives the number of consecutive *PARTIAL ASPIRATION* displayed in the After # Runs field. Control runs will not AutoStop if the only flag encountered during the run is 'P'.

This AutoStop cannot be disabled.



Place an update label next to heading **Deleting Patient Data** on page 7-3 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

PATIENT RECORDS DELETION WINDOW

You requested to delete sample information. The requested information has not yet been deleted. To Delete Data

1. On the Patient Data - DELETION REQUESTED window, verify the data you want to delete:

If you Select

This Data is Deleted

All Data For Record(s)

All histogram, DataPlot, 3D, 2D, numeric data and demographic information.

Note: The demographic information (patient record) is not deleted from the database unless the GENS Workstation software is restarted and there are no other sample records in the database associated with that patient record.

Delete Only Partial Data For Record(s)

List Mode Data

3D Dataplot data originally transmitted from the Analyzer. Numeric data remains in the database.

Graphics Data

All histogram and 2D DataPlot data. 3D Dataplot data and Numeric data remains in the database.

2. Select . A PATIENT RECORD(S) DELETION window appears. The requested information has still not been deleted.
3. Select  to delete the sample information. You will no longer be able to retrieve the information.

To Keep the Data

Select  on either patient deletion window to keep the sample information. The deletion windows close.



Place an update label next to heading **Printing** on page 7-4 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

PRINTING

1. Select the items you want to print.
 - If you are currently viewing the Results & Graphics window, only the current results can be printed.
 - If you are currently viewing the DataBase & ToDo window, you can select several items that appear in the list and print them as a batch.
2. Select  to display the Output Selection window.
3. Verify that the Output Selection window identifies the items you want to print.
4. Select  to print the items. The Workstation sends the selected items to the default printer based on the settings you verified.

Printing Help Topics

To print a Help topic you are currently viewing select .

To print a popup Help window, use your right mouse button to click inside the popup window, and then select Print Topic.

Note: Reference Information, Cleaning Procedure, and Replacing Procedure Help Topics that display full screen should be printed using Landscape Orientation.



Place an update label next to heading **5.7, Processing Results Overview** on page 5-7 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

PROCESSING RESULTS OVERVIEW

The COULTER GEN•S System provides many functions to help you identify and process results quickly and effectively. The Workstation includes flags and codes with results to help you. You can also customize the flagging of results and define rules for flagging sample results.

Flagging

The Workstation assigns priorities to flags. Critical flags (cH/cL) are the most important. They are followed by action flags (aH/aL) and then default flags(H/L).

IMPORTANT Flagging is evaluated when the sample is analyzed. Flagging is reevaluated for a sample when the results are manually edited, or when new results are received for a pending sample. Flagging is not reevaluated upon a change of flagging limits for results already in the database. Delta Check and Reflex Decision Rules are not reevaluated.

IMPORTANT Coulter Corporation does not claim to identify every abnormality in all samples. Coulter suggests using all available flagging options to optimize the sensitivity of instrument results. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

You can customize many of the flags to suit the needs of your laboratory. You can define:

- Default high/low limits
- Different high/low limits based on gender and age
- Different high/low limits based on location
- Action limits that exceed the default limits. These appear with a unique aH (action high) and aL (action low) flags
- Critical limits that exceed the action limits. These appear with a unique cH (critical high) and cL (critical low) flags
- Limits (action) that force the display of definitive messages
- Limits that route results to a special Review Folder (AutoVerification).

Of course, you do not need to define these all at once, you can use the default set and gradually add additional limits based on your laboratory's assessment.

Rules for Flagging Results (Decision Rules & Criteria)

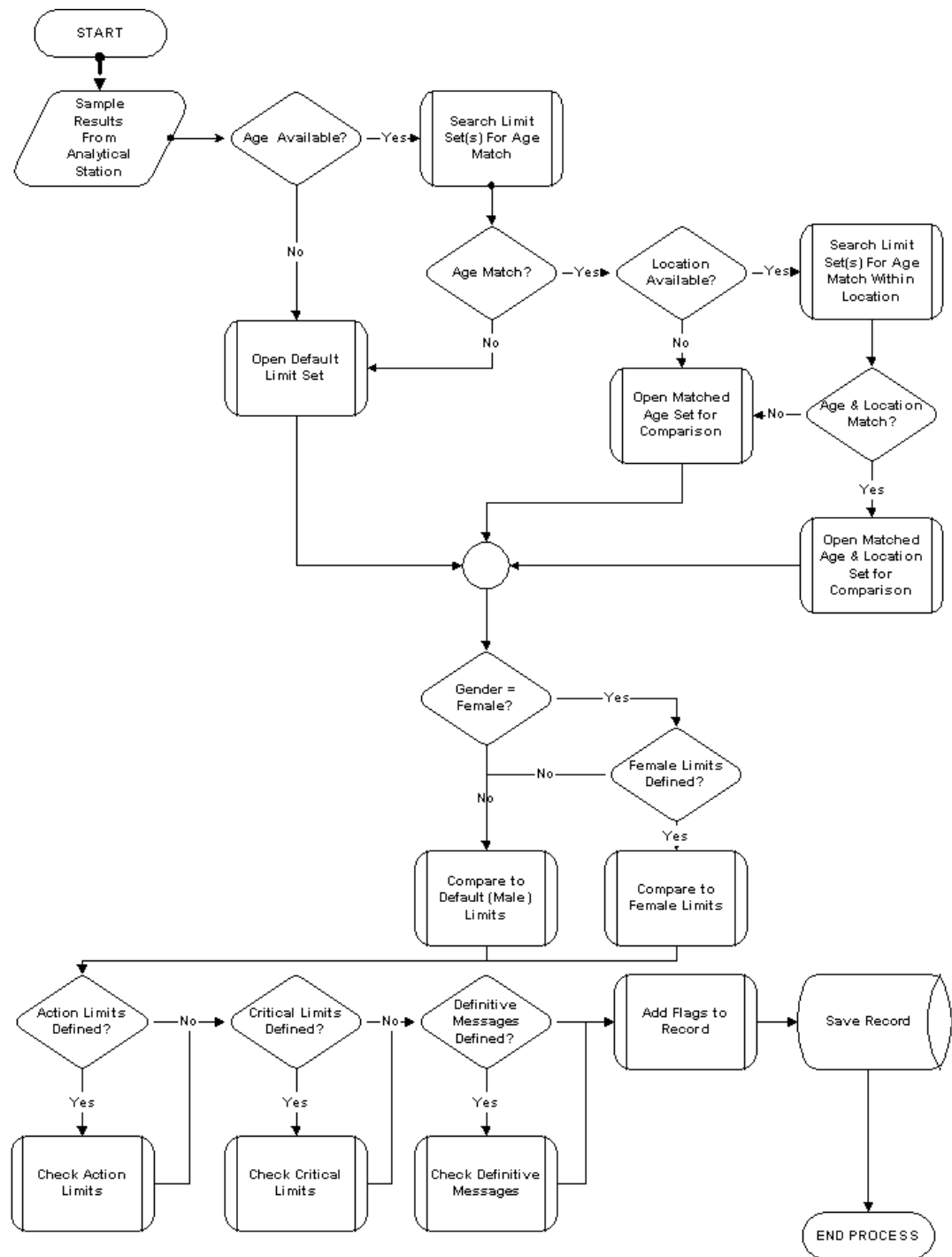
You can define rules for delta checking. When the Workstation finds a sample for a patient that already has sample results in the DataBase, it uses the rules you define to determine how to flag the sample.

You can also define rules (Reflex Manager) to identify sample results that meet a set of criteria. For example, you can automatically generate the message "Perform Retic Count" in the comment field if the Workstation receives a sample result with Hgb $\leq$ 10.5 or RBC $\leq$ 3.2 and MCV $\leq$ 65.

As part of your rule definition, you can specify where you want the results that satisfy the rule to appear. For example, the Workstation can route results to special Reflex Manager, Delta Check and Review folders.

Processing Flagging Limits

The following flow chart illustrates how the system processes flagging limits.





Place an update label next to step 5 on page 8-19 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

REPLACE DLE E WITH DLE C



indicates the Workstation replaces DLE E with DLE C in the standard data set transmitted to your information system.



Place an update label next to step 4 on page 8-17 of your GEN•S Operator's Guide, PN 4237222B, for the following new information:

REPORT FORMAT

1. Select  to display a list of available report formats.
2. Select one of the following:

GEN•S	To use the GEN•S chartable or in-lab report layout (8.5 by 11.5 inch paper format)
STKS	To use the STKS-like report layout (8.5 by 11.5 inch paper format)
ONYX	To use the ONYX-Like chartable or in-lab report layout (8.5 by 11.5 inch paper format).
MAXM	To use the MAXM-like report layout (5.5 by 6.5 paper format).

The following table identifies options that are unique to specific formats:

Option	GEN•S	STKS	ONYX	MAXM
Chartable Report	✓		✓	
Manual Diff Box	✓		✓	
Reference Interval	✓		✓	



Place an update label next to heading 8.23, **Run Configuration Window** on page 8-30 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

RUN CONFIGURATION WINDOW

This window allows you to quickly change standard options for individual tests or studies you may perform.

Changes to this window take effect the next time the Workstation receives a sample. The changes remain in effect until you or another user change the options again.

You can change:

- Which results to print
- Which default report you want to use
- Which results to transmit to your information system
- When to make a slide
- Whether results are stored as part of quality assurance information
- Which results should cause the instrument to stop processing
- Whether the Decision Criteria Rules are used
- Whether the AutoNumbering option is used
- Whether the AutoCollation option is used.
- Whether to enable SlideMaker Communication
- Whether to limit independent flags H&H Check Failed and Pancytopenia.

No Match, No Read and Partial Aspiration are not flags, but Run Status messages. As a selectable item within Run Configuration, these Run Status messages are not included in 'Any Flags'. If you wish to implement a function based on all flags and the Run Status message, select Specific Flags, then select all the pertinent checkboxes.

Research flags are included in 'Any Flags', but are not included in 'Suspect'. If you wish to implement a function based on all Suspect flags, including the Research flags, select Specific Flags, then select all the pertinent checkboxes.



Place an update label next to heading **Running Latex Control—Diff** on page 3-1 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

RUNNING LATEX CONTROL—DIFF

1. Check the instrument processing control on the Command Center.
2. Ensure the latex primer and control are within the correct temperature range. For COULTER LATRON primer and control the correct temperature range is 18-30°C/64-86°F.
3. Verify the lot number of the primer and control. If you must use a new lot number, ensure that it has been set up properly.

CAUTION Possible system damage could occur if you aspirate anything except latex control or latex primer using this function. Do not aspirate any other materials with this function.

4. Go to the Diluter Keypad.

5. Press **F 5 5 ENTER** to aspirate latex for the Diff test mode. The Diluter Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.

6. Press **CLEAR APERT**. The Diluter Keypad displays *PRESS MANUAL OR PRESENT SAMPLE*.

7. Remove the cap of the latex primer vial.
8. Immerse the aspirator tip in the latex primer vial. The instrument automatically aspirates the primer. The Diluter Keypad displays *DIFF PRIMER* while the instrument performs this function. When this function completes processing, the Diluter Keypad displays *FUNCTION = 55*.

Tip: When using Manual aspiration mode, the instrument automatically aspirates the sample. If the instrument fails to aspirate the sample, the optical sensors on the activator may be malfunctioning.

Press the black activator that surrounds the aspirator tip to aspirate the sample, and call your Coulter Representative.

9. Remove the vial from the aspirator tip when you hear a beep and the Analyzer Status line displays *PREPARING SAMPLE*. The probe cleaner retracts the aspirator and automatically cleans it.
10. At the Workstation, check the results from the primer.
11. If the results in the PRIMER column are less than or equal to 500, proceed to step 12. Otherwise, if the results in the PRIMER column are greater than 500:

- a. At the Diluter Keypad, press **ENTER** to reactivate the function for the control. The Diluter Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.
- b. Perform steps 7 through 9 up to three more times.
- c. If you do not get a result below 500, cycle a new vial of primer.
- d. If you still do not get a result below 500, call your Coulter Representative.

12. At the Diluter Keypad, press **ENTER** to reactivate the function for the latex control. The Diluter Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.

IMPORTANT Erroneous results could occur if you press *CLEAR APERTURE* before aspirating latex control. *CLEAR APERTURE* is only used before aspirating latex primer in this procedure.

13. Gently mix the latex control according to the directions in the package insert.
14. Immerse the aspirator tip in the latex control vial. The instrument automatically aspirates the control.
The Diluter Keypad displays *LATEX—DIFF* while the instrument performs this function. When this function completes processing, the Diluter Keypad displays *FUNCTION = 55*.
15. At the Workstation, verify the results from the control.
16. At the Diluter Keypad, press **STOP** to exit this function. The Diluter Keypad displays *READY*.



Place an update label next to heading **Running Latex Control—Diff And Retic** on page 3-3 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

RUNNING LATEX CONTROL—DIFF AND RETIC

1. Check the instrument processing control on the Command Center.
2. Ensure the latex primer and control are within the correct temperature range. For COULTER LATRON primer and control the correct temperature range is 18-30°C/64-86°F.
3. Verify the lot number of the primer and control. If you must use a new lot number, ensure that it has been set up properly.

CAUTION Possible system damage could occur if you aspirate anything except latex control or latex primer using this function. Do not aspirate any other materials with this function.

4. Go to the Diluter Keypad.

5. Press **F 5 7 ENTER** to aspirate LATEX primer and LATEX control for combined Diff and Retic test modes. The Diluter Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.

6. Press **CLEAR APERT**. The Diluter Keypad displays *PRESS MANUAL OR PRESENT SAMPLE*.

7. Remove the cap of the latex primer vial.

8. Immerse the aspirator tip in the latex primer vial. The instrument automatically aspirates the RETIC+DIFF primer. The Diluter Keypad displays *RETIC+DIFF PRIMER* while the instrument performs this function. When this function completes processing, the Diluter Keypad displays *FUNCTION = 57*.

Tip: When using Manual aspiration mode, the instrument automatically aspirates the sample. If the instrument fails to aspirate the sample, the optical sensors on the activator may be malfunctioning.

Press the black activator that surrounds the aspirator tip to aspirate the sample, and call your Coulter Representative.

9. Remove the vial from the aspirator tip when you hear a beep and the Analyzer Status line displays *PREPARING SAMPLE*. The probe cleaner retracts the aspirator and automatically cleans it.
10. At the Workstation, check the results from the primer.
11. If the results in the PRIMER column are less than or equal to 500, proceed to step 12. Otherwise, if the results in the PRIMER column are greater than 500:

- a. At the Diluter Keypad, press **ENTER** to reactivate the function for the control. The Diluter Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.
- b. Perform steps 7 through 9 up to three more times.
- c. If you do not get a result below 500, cycle a new vial of primer.
- d. If you still do not get a result below 500, call your Coulter Representative.

12. At the Diluter Keypad, press **ENTER** to reactivate the function for the latex control. The Diluter Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.

IMPORTANT Erroneous results could occur if you press CLEAR APERTURE before aspirating latex control. CLEAR APERTURE is only used before aspirating latex primer in this procedure.

13. Gently mix the latex control according to the directions in the package insert.
14. Immerse the aspirator tip in the latex control vial. The instrument automatically aspirates the control. The Diluter Keypad displays *RETIC+DIFF--LATEX* while the instrument performs this function. When this function completes processing, the Diluter Keypad displays *FUNCTION = 57*.
15. At the Workstation, verify the results from the control.
16. At the Diluter Keypad, press **STOP** to exit this function. The Diluter Keypad displays *READY*.



Place an update label next to heading **Running Latex Control—Retic** on page 3-2 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

RUNNING LATEX CONTROL—RETIC

1. Check the instrument processing control on the Command Center.
2. Ensure the latex primer and control are within the correct temperature range. For COULTER LATRON primer and control the correct temperature range is 18-30°C/64-86°F
3. Verify the lot number of the primer and control. If you must use a new lot number, ensure that it has been set up properly.

CAUTION Possible system damage could occur if you aspirate anything except latex control or latex primer using this function. Do not aspirate any other materials with this function.

4. Go to the Diluter Keypad.
5. Press **F 5 6 ENTER** to aspirate latex for Retic test mode. The Diluter Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.
6. Press **CLEAR APERT**. The Diluter Keypad displays *PRESS MANUAL OR PRESENT SAMPLE*.
7. Remove the cap of the latex primer vial.
8. Immerse the aspirator tip in the latex primer vial. The instrument automatically aspirates the primer. The Diluter Keypad displays *RETIC PRIMER* while the instrument performs this function. When this function completes processing, the Diluter Keypad displays *FUNCTION = 56*.

Tip: When using Manual aspiration mode, the instrument automatically aspirates the sample. If the instrument fails to aspirate the sample, the optical sensors on the activator may be malfunctioning.

Press the black activator that surrounds the aspirator tip to aspirate the sample, and call your Coulter Representative.

9. Remove the vial from the aspirator tip when you hear a beep and the Analyzer Status line displays *PREPARING SAMPLE*. The probe cleaner retracts the aspirator and automatically cleans it.
10. At the Workstation, check the results from the primer.
11. If the results in the PRIMER column are less than or equal to 500, proceed to step 12. Otherwise, if the results in the PRIMER column are greater than 500:
 - a. At the Diluter Keypad, press **ENTER** to reactivate the function for the control. The Diluter Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.
 - b. Perform steps 7 through 9 up to three more times.
 - c. If you do not get a result below 500, cycle a new vial of primer.
 - d. If you still do not get a result below 500, call your Coulter Representative.

12. At the Diluter Keypad, press **ENTER** to reactivate the function for the latex control. The Diluter Keypad displays *PRESS MANUAL OR CLEAR APERTURE*.

IMPORTANT Erroneous results could occur if you press *CLEAR APERTURE* before aspirating latex control. *CLEAR APERTURE* is only used before aspirating latex primer in this procedure.

13. Gently mix the latex control according to the directions in the package insert.
14. Immerse the aspirator tip in the latex control vial. The instrument automatically aspirates the control. The Diluter Keypad displays *RETIC--LATEX* while the instrument performs this function. When this function completes processing, the Diluter Keypad displays *FUNCTION = 56*.
15. At the Workstation, verify the results from the control.
16. At the Diluter Keypad, press **STOP** to exit this function. The Diluter Keypad displays *READY*.



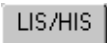
Place an update label next to heading 8.11, **Setting Up Rules for Flagging Sample Results** on page 8-15 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

SETTING UP AUTOVALIDATION

Before performing this procedure, read the Autovalidation Overview so that you understand how the GEN•S software assigns validation codes to sample results.

Enable AutoValidation Codes

Enable the AutoValidation codes on the Communications screen if you want the validation codes to be transmitted to your information system. These codes will always print on the patient reports even if disabled on this screen. To enable transmission of the validation codes:

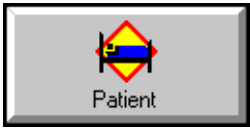
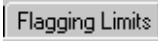
1. Select  on the Command Center to display the System Setup window.
2. Select  to display the System Setup Communications window.
3. Select the  tab.
4. Select  Enable Validation Codes.
5. Select  to save the changes.

Enable AutoVerification Criteria

The system allows you to configure AutoVerification for Reference, Action and Critical limits and also for Definitive messages for each Flagging Range that you set up in the Workstation.

If you have not set up flagging limits for your laboratory, follow the steps in Setting Up Flagging Limits to assign limits and enable Verification criteria.

If your flagging limits have already been set up and you want to enable Verification Criteria for either Reference, Action and Critical limits or Definitive messages, then perform the following.

1. Select  on the Command Center to display the System Setup window.
2. Select  to display the System Setup - Patient window.
3. Select  to display the limits table.
4. Select the limit name you want to configure with Verification Criteria.

5. Select  to display the Laboratory Flagging Limits Setup window.
6. Select the limits tab that you want Verification Criteria enabled on.
7. Select  AutoVerification Criteria.
8. Select  to save the changes.

Repeat steps 3 through 8 for each limit that you want enabled.

Setup Decision Rules

Setup Decision rules for your laboratory. If Decision Rules are enabled and a decision rule is met for a sample, this will cause an AutoValidation failure.

IMPORTANT REVIEW DECISION RULES THAT CONTAIN MULTIPLE PARAMETERS. If you create a rule that has more than one parameter or contains more than one item that is related to a parameter, all of the parameters included in the rule (even if an OR condition is used) **must also** be included in the parameters reported in your report profile. Refer to Example A.

Example A:

<u>Rule Setup:</u>	Reflex rule is defined as "If WBC is < 2.0 OR Hgb is < 6.0 then Repeat sample and call results".
<u>Sample Setup:</u>	Test Mode = CBC
<u>Preassigned Sample:</u>	includes only Hgb and Hct (Report Name) (As printed and transmitted to LIS.)
<u>Sample Results:</u>	Hgb 5.8 g/dL Hct 17.8 %

Note: The decision rule will not be applied to this sample even though the Hgb value is below 6.0. This is because the WBC parameter is not reported. In order for the Decision Rule to be applied to the sample, all parameters in the rule have to be reported. Therefore this sample would not result in an autovalidation failure since the decision rule was not applied.

IMPORTANT If the Validation Codes are going to be used on either the printout or in the LIS, all parameters specified in a rule must be included in a parameter block in order for all of the Validation codes to be CORRECT. Refer to Example B.

Example B:

<u>Rule Setup:</u>	Reflex rule is defined as "If Hgb < 6.5 OR Hct < 19.5 then Rerun Sample and Phone Results".
<u>Sample Setup:</u>	Test Mode = CBC
<u>Preassigned Sample:</u>	Report all CBC parameters (Report Name),
<u>Sample Results:</u>	(As printed and transmitted to LIS.) WBC 4.8 10 ³ /L RBC 2.53 10 ⁶ /L Hgb 6.3 g/dL Hct 19.6 % MCV 77.4 fL MCH 24.9 pg MCHC 32.1 g/dL RDW 16.1 % Plt 80 10 ³ /L MPV 10.3 fL

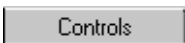
Note: The parameter blocks that will be evaluated against the Decision Rule are the H and C blocks, because both Hgb and Hct are included in these blocks. The Decision Rule is not applied to the W block because Hct is not included in this block. Therefore, the AutoValidation message/codes will print and transmit "Sample Not Validated, C NV, H NV, W AV". In order for the Decision Rule to be applied to the W block, you must create a Decision rule for Hgb and then a Decision rule for Hct, in order to get "Sample Not Validated, C NV, H NV, W NV". .



Place an update label next to heading 8.3, **Setting Up Controls** on page 8-2 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SETTING UP CONTROLS

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select  on the Command Center to display the System Setup window.
2. Select  to display the Quality Assurance Setup window.
3. Select  to display the control information already set up for your instrument.
4. Select . The Setup New Controls Folder window appears.
5. Select the source of the control materials.
6. Select the type of control.

7. Select the level of the control you want to set up.

8. Select  to specify the reference values and ranges for the control. The window you see varies depending on the source and type of control you selected.

Note: A reference RBC is used to calculate the reticulocyte absolute number for Retic only samples. All other samples use the RBC value obtained during CBC, CR or CDR analysis.

9. Perform one of the following depending on the source and type of control:

This Control	Do This
Coulter (non-latex)	Follow the instructions on the Diskette Entry of Lot Specific Information window.
Patient or Other (non-latex)	Specify non-latex reference values.
Latex	Specify latex reference values.

10. If desired, select  to set up lab limits for the control.

11. Select



To return to the System Setup window.

Another tab

To change additional Quality Assurance Setup information. The Workstation asks you if you want to save the changes you made to the current information. Select  to proceed.

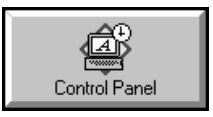


Place an update label next to heading **Setting Up Date And Time** on page 8-28 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SETTING UP DATE AND TIME

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select  to display the System Setup window.

2. Select  to display the Windows NT™ Control Panel.

3. Double-click  to display the Windows NT Date/Time window.

4. Specify the details for date and time. If you need additional information about the fields on the Date/Time window, select  .
5. Shutdown and restart the Workstation after adjusting clock time.
Note: Service selects workstation regional, date and time settings at installation. Call Service if you desire modification of a regional setting. Modifications attempted at the LabAdmin security level may cause incorrect displays of information such as date format in some applications.
6. Read about GEN•S Year 2000 features.



Place an update label next to heading 8.10, **Setting Up Flagging Limits** on page 8-12 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SETTING UP FLAGGING LIMITS

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

IMPORTANT Flagging is evaluated when the sample is analyzed. Flagging is reevaluated for a sample when the results are manually edited, or when new results are received for a pending sample. Flagging is not reevaluated upon a change of flagging limits for results already in the database. Delta check and Reflex Decision Rules are not reevaluated.

IMPORTANT Coulter suggests using all available flagging options to optimize the sensitivity of instrument results. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

1. Select  on the Command Center to display the System Setup window.
2. Select  to display the Patient Setup window.
3. Select  to display the list of flagging limits set up for your laboratory.
4. Select  to create a new limit.
5. Type the name you want associated with the attributes you specify.
6. Specify the location you want associated with the limit.
7. Specify the age range you want associated with the limit.
Note: Use the age range monitor to ensure you do not specify overlapping ranges for the same location.

8. Select  on the Setup New Limit Set window to save the limit name, location and age range.

9. Select the limit name that you want to set the flagging limits for.

10. Select  and display the Laboratory Flagging Limits Setup window.

11. Specify whether you want to AutoVerify the results that match this limit.

12. Type the lower and upper limits for each parameter of the default Male category. Use



to move between fields.

13. Select:

Female	To define low and high limits for samples originating from a female and whether you want to AutoVerify the results that match this list.
Action Limits	To define low and high limits for samples that require action by your laboratory and whether you want to AutoVerify the results that match this list.
Critical Limits	To define low and high limits for samples that are critical and require immediate action by your laboratory and whether you want to AutoVerify the results that match this list.
Definitive Limits	To identify the definitive messages you want to appear and whether you want to AutoVerify the results that match this list.

14. Repeat steps 9 through 12 for each category you want to use for this limit name.

15. Select . The Workstation saves the limit information with the limit name and returns you to the Flagging Limits tab on the Patient Setup window. The Workstation flags future sample results based on the attributes you specified. If you review existing results in the database, they appear with the OLD attributes.

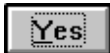
16. Select:



To close the Patient Setup window and return to the System Setup window.

Another tab

To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current

information. Select  to proceed.



Place an update label next to heading 8.14, **Setting Up Lis / His Communications** on page 8-18 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SETTING UP LIS / HIS COMMUNICATIONS

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Consult with your information system administrator to ensure you have the correct information to perform this procedure. Also ensure your information system administrator has the latest Host Transmission manual, PN 4237306.
2. Select  on the Command Center to display the System Setup window.
3. Select  to display the Communications window.
4. Select  to display the communications settings for transmitting data from all your instruments to your information system.
5. Select whether to transmit validation codes to your information system.
6. Select whether to Replace DLE E with DLE C in the standard data set transmitted to your information system.
7. Select the time out interval you want used.
8. Select the baud rate your information system can receive.
9. Select the type of parity you want used for communications with your information system.
10. Select the stop bits for your information system.
11. Select the data bits you want used for transmission to your information system.
12. Select the block size for transmissions to your information system.
13. Select the data format for compatibility.
14. If a handshake with your information system is necessary, verify that **Handshake** is turned on.
15. If you specified the GEN•S compatibility format, specify the graphics data you want to transmit to your information system.
16. Select:



To close the Communications Setup window and return to the System Setup window. The next time the Workstation transmits a result to your information system, it transmits the result with the settings you specified.

Another tab

To change additional Communications Setup information. The Workstation asks you if you want to save the changes you made to

the current information. Select  to proceed.



Place an update label next to heading 8.9, **Setting Up Reporting Units** on page 8-12 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SETTING UP REPORTING UNITS

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. Select  on the Command Center to display the System Setup window.
2. Select  to display the Patient Setup window.
3. Select  to display the reporting information for your Workstation.
4. Select the reporting units format for your laboratory. You can create formats SI5, SI6 and SI7 by selecting **CUSTOM** and then specify the units for each parameter.
5. Specify the groups of parameters you want to display with an extra digit.
Note: You must reset the Workstation after each time you select or deselect extra digit.
6. Select:



Another tab

To save the changes. The Workstation stores the changes and updates the date last modified and the user name. The Workstation updates the reporting units immediately.

To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current information. Select  to proceed.



Place an update label next to heading 8.11, **Setting Up Rules for Flagging Sample Results** on page 8-15 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SETTING UP RULES FOR FLAGGING SAMPLE RESULTS

Note: To perform this task, you must log on with a user name that was set up as a Lab Administrator. If you need to access this function, contact your laboratory administrator.

IMPORTANT Flagging is evaluated when the sample is analyzed. Flagging is reevaluated for a sample when the results are manually edited, or when new results are received for a pending sample. Flagging is not reevaluated upon a change of flagging limits for results already in the database. Delta check and Reflex Decision Rules are not reevaluated.

IMPORTANT Coulter suggests using all available flagging options to optimize the sensitivity of instrument results. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

1. Select  on the Command Center to display the System Setup window.
2. Select  to display the Patient Setup window.
3. Select **Decision Rules & Criteria** to display a list of the existing rules set up for your laboratory.
4. Select  to create a new rule.
5. Check that the rule environment is set up the way you want.
6. Specify the rule name.
7. Specify the type of rule.
8. Specify a short description of the rule.

IMPORTANT REVIEW YOUR DECISION RULES THAT CONTAIN MULTIPLE PARAMETERS. If you create a rule that has more than one parameter or contains more than one item that is related to a parameter, all of the parameters included in the rule (even if an OR condition is used) must also be included in the parameters reported in your report profile. Refer to Example A.

9. Define the delta check criteria or the reflex manager criteria.
10. Select  to return to the Patient Setup Decision Rules & Criteria tab.
11. Select:

 or  in the enabled column.

To enable or disable decision rules individually.



To close the Patient Setup window and return to the System Setup window. The Workstation tests for the rule you defined the next time it receives a sample result.

Another tab

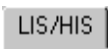
To change additional Patient Setup information. The Workstation asks you if you want to save the changes you made to the current information. Select  to proceed.

Note: If decision rules are to be used for sample flagging, the decision rules must be enabled on the Decision Rules & Criteria screen and Decision Criteria must be enabled on the Run Configuration screen



Place an update label next to heading **Setting Up Which Results To Transmit Automatically** on page 8-32 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SETTING UP WHICH RESULTS TO TRANSMIT AUTOMATICALLY

1. Select  to display the Run Configuration window.
2. Select  as the type of Automatic Output.
3. Select the flag type you want to use to determine which results are sent to the information system.
4. Select  to save the changes. For any instrument connected to the Workstation, the next results are sent to the laboratory computer based on the flags you selected.

See Setting Up LIS / HIS Communications for information about settings used for transmitting results to your laboratory computer.



Place an update label next to heading **Setting Up Which Results to Print Automatically** on page 8-31 and heading **Setting Up Which Results to Transmit Automatically** on page 8-32 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SPECIFIC FLAGS

Select **Specific Flags** to activate these fields. These fields appear for each type of Automatic Output. The fields allow you to control which samples the Workstation sends to the output device. Select one or more:

Field	Results Sent When Flagged With
Reference Interval	L or H.
Action Limits	aL or aH.
Critical Limits	cL or cH.
Definitive Messages	Definitive messages.
No Flags	Without any flags. Generally, this is used in combination with another indicator, such as Definitive Messages.
Delta Check	Delta check. This selection is not available when you select the SlideMaker tab.
Partial Aspiration	Partial aspiration in the Status field. This selection is not available when you select the SlideMaker tab.
No Read	No read in the Status field.
No Match	No match in the Status field.
Suspect Messages	Suspect messages.
Reflex Manager	Reflex Manager message. This selection is not available when you select the SlideMaker tab.
Research Flags	Research flags



Place an update label next to heading **Specifying Latex Reference Values** on page 8-3 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SPECIFYING LATEX REFERENCE VALUES

Note: Before performing this procedure, you must perform steps 1 through 8 of Setting Up Controls.

1. Specify whether or not you want results automatically transmitted to your information system.
2. Type the lot number of the latex control and press .
3. Type the expiration date of the control and press .
4. Specify whether you want to use this lot number as a default.
5. Type the values in the appropriate fields:
 - Diff Mode Parameters
 - Retic Mode Parameters
6. Select



To save the reference values and return to the Setup New Control Folder window.



To return to the Setup New Control Folder window without saving changes.



Place an update label next to heading **8.12 Setting Up Reports** on page 8-17 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

STKS-LIKE REPORT FORMAT

Algorithm Revision Numbers

A value is printed above the Institution Name that indicates the revision of the differential and reticulocyte algorithm installed. The release is indicated as D:X.X [00000] R:X.X. The values in brackets indicate the Differential Preference selections made by Lab Administration. Differential Preference selections are the low level (1), mid level (2) or high level (3).

Report Comments

Decision Rules & Criteria messages appear in the comment area.

Printed Report Footer

Any or all of the following footers can appear when you print a report:

This footer

End of completed report

End of preliminary report

Means This

The sample was not preassigned in the ToDo list or all the test requests for the sample are completed.

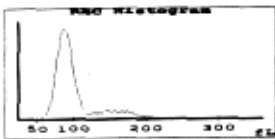
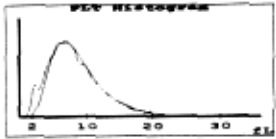
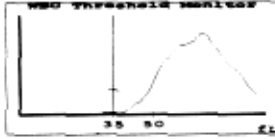
At least one test request for the sample is pending.

End of additional tests report After the sample was run and printed with an End of completed report footer, an additional test was requested and run.

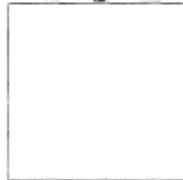
Blood Detector disabled The sample was run with the blood detector disabled.

SYSTEM ALARM A system alarm occurred when this sample was run.

2/25/99 16:35:12 Page 1 of 3 SER	Coulter Technology Center D:10.0(13231) (800) 526-4932	Coulter Corporation P. O. Box 249015 Miami, FL 33116-9015
--	--	---



CD	Case / Pos	Sample ID	Date	Time	Run Status	Instrument	Operator
A	003611	-----	1/28/99	16:06:23	Completed	237010	SER

Patient ID Gender Location Physician Date of Birth Comments:	Last Name Seq # Age	First Name Drawn Date User Field 1 User Field 2 User Field 3
---	---------------------------	--

WBC 5.7 10 ³ /μL NE % 58.5 % LY % 28.9 % MO % 10.1 % EO % 2.2 % BA % 0.3 % NE # 3.4 10 ³ /μL LY # 1.7 10 ³ /μL MO # 0.6 10 ³ /μL EO # 0.1 10 ³ /μL BA # 0.0 10 ³ /μL	RBC 4.38 10 ⁶ /μL HGB 13.2 g/dL HCT 39.8 % MCV 90.6 fL MCH 30.2 pg MCHC 33.2 g/dL RDW 13.3 % RET % RET #	PLT 287 10 ³ /μL MPV 8.9 fL CD4 % CD8 % CD4 # CD8 # CD4:8
---	--	--

Suspect/Definitive Messages:

End of Completed Report, Sample Not Validated, C AV, D AV, H AV, W AV / 01B1893B



Place an update label next to heading 4.2, **Storing Specimens** on page 4-1 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

STORING SPECIMENS

Analyze specimens as soon as possible for optimum accuracy.

Tip: For more information on handling and processing blood specimens, refer to NCCLS publication H18-A.

Venipuncture Specimens

For CBC and DIFF:

- Run within 24 hours after collection if stored at room temperature (23.9°C or 75°F).
- Run within 48 hours after collection if stored at 2 to 8°C (35.6 to 46.4°F).

For Reticulocytes:

- Run within 24 hours after collection if stored at room temperature (23.9°C or 75°F).
- Run within 72 hours after collection if stored at 2 to 8°C (35.6 to 46.4°F).

Capillary Specimens

Follow the manufacturer's recommendations for the microcollection device.



Place an update label next to heading 5.9, **Suspect And Definitive Messages** on page 5-12 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

SUSPECT AND DEFINITIVE MESSAGES

IMPORTANT Coulter Corporation does not claim to identify every abnormality in all samples. Coulter suggests using all available flagging options to optimize the sensitivity of instrument results. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, parameter codes, delta checks, decision rules and system alarms. Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

Suspect Messages

Suspect messages appear for sample results based on an abnormal cell distribution or population. The system generates these messages according to an internal algorithm.

All sample results with suspect messages automatically appear in the Review Folder. Review the sample according to your laboratory's procedures. If you observe a higher rate of suspect flags than usual call your Coulter Representative.

Message	Notes	Source
Abnormal Retic Pattern	This message appears when any of the following appear on the Research Data window: Sickle, Thalassemia or RET Interference.	Retic
Aging Sample	Pattern started shifting because of aging. This message appears on the Research Data window only.	Diff
DDD	Data Discontinuity. The instrument used data only while the flow rate was good. This flag appears on the Research Data window only.	Diff or Retic
Dimorphic Reds	Two populations of RBCs.	CBC
Giant Platelets	Giant Platelets.	CBC
Imm. NE1	Immature neutrophil 1 (immature neutrophils and/or bands).	Diff
Imm. NE 2	Immature neutrophil 2 (metamyelocytes, myelocytes, promyelocytes).	Diff
RET Interference	Refers to the Reticulocyte measurement. This message appears on the Research Data window only.	Retic
Low Opacity LY	Low opacity lymphocytes. This message appears on the Research Data window only.	Diff
Low Volume LY	Low volume lymphocytes. This message appears on the Research Data window only.	Diff
Low Volume WBC	This message appears on the Research Data window only. It appears when particles that may be NRBC or extremely small WBC are noted and excluded from the Ret% during reticulocyte analysis.	Retic
Low Event #	Refers to the fact that a less than optimum number of events were collected for analysis. R appears next to DIFF% and DIFF# when this message appears.	
LY Blast	Suspect blast in the lymphocyte area of the dataplot.	Diff
Micro/Fragmented Reds	The instrument suspects the presence of microcytic red blood cells or fragmented red blood cells.	CBC
MO Blast	Suspect blast in the monocyte area of the dataplot.	Diff

Mode < 3 or > 15	Platelet no fit because mode not between 3 and 15. This message appears on the Research Data window only. R appears for Plt, Pct, MPV, and PDW.	CBC
NE Blast	Suspect blast in the neutrophil area of the dataplot.	Diff
Non-positive Curve	Platelet no fit because non-positive curve. This message appears on the Research Data window only. R appears for Plt, Pct, MPV, and PDW.	CBC
NRBC	Nucleated RBCs.	Diff
PDW >20	Platelet no fit because PDW >20. This message appears on the Research Data window only. R appears for Plt, Pct, MPV, and PDW.	CBC
Platelet Clumps	Platelet clumps.	CBC
Platelet Interference	This message appears on the Research Data window only. This appears in conjunction with Plt R .	
Plt <20	Platelet no fit because Platelet <20. This message appears on the Research Data window only. R appears for Plt, Pct, MPV, and PDW.	CBC
RBC Interference	This message appears on the Research Data window only. This appears in conjunction with Plt R .	
Red Cell Agglutination	Red cell clumping may be present.	CBC
Sickle	This message appears on the Research Data window only. This refers to the Reticulocyte measurement and contributes to the Abnormal Retic Pattern message.	Retic
Thalassemia	This message appears on the Research Data window only. This refers to the Reticulocyte measurement and contributes to the Abnormal Retic Pattern message.	Retic
Total voteout of fitted curve	Platelet no fit because total voteout of fitted curve. This message appears on the Research Data window only. R appears for Plt, Pct, MPV, and PDW.	CBC
Variant LY	Variant lymphocytes	Diff
Verify Diff	R appears next to DIFF% and DIFF# when this message appears. Verify differential results according to your laboratory's protocol.	Diff
Verify Retic	R appears next to RET% and RET# when this message appears. Verify retic results according to your laboratory's protocol.	Retic

WBC Exceeds Linearity	This message appears on the Research Data window only. This appears in conjunction with Platelet R flag.
WBC Interference	This message is displayed as a suspect flag whenever WBC* is present

Definitive Messages

Definitive messages appear for sample results based on action limits exceeded for age only. The messages are set up as part of your flagging limits.

Message	Result Exceeds	Notes
Anemia	Low limit for RBC or Hgb	Pancytopenia overrides this message.
Anisocytosis (with gradient ranges)	High limit for RDW	
Basophilia	High limit for BA% or BA#	
Eosinophilia	High limit for EO% or EO#	
Erythrocytosis	High limit for RBC	
H&H Check Failed	Hct < ((Hgb*3) - 3) OR Hct > ((Hgb * 3)+3)	
Hypochromia (with gradient ranges)	Low limit for MCH	
Large Platelets	High limit for MPV	
Leukopenia	Low limit for WBC	Pancytopenia can override this message, if it is enabled.
Leukocytosis	High limit for WBC	
Lymphopenia	Low limit for LY% or LY#	
Lymphocytosis	High limit for LY% or LY#	
Macrocytosis (with gradient ranges)	High limit for MCV	
Microcytosis (with gradient ranges)	Low limit for MCV	
Monocytosis	High limit for MO% or MO#	
Neutropenia	Low limit for NE% or NE#	
Neutrophilia	High limit for NE% or NE#	

Pancytopenia	Low limit for WBC, RBC and Plt	This message can override messages for Anemia, Leukopenia and Thrombocytopenia, if it is enabled. The system generates this message automatically.
Reticulocytosis	High limit for RET% or RET#	
Small Platelets	Low limit for MPV	
Thrombocytopenia	Low limit for Plt	Pancytopenia overrides this message.
Thrombocytosis	High limit for Plt	



Place an update label next to heading **Turning Autostop Off/On** on page 8-3 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

SYSTEM STOP CRITERIA

The GEN•S System includes several functions that enable you to stop processing samples. You can specify any of the following for AutoStop:

- Flow cell
- Controls
- XB/XM
- SlideMaker
- No Match
- No Read
- Partial Aspiration



Place an update label next to heading **Archiving** on page 7-6 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

TIP: ARCHIVING INFORMATION

When you archive information, the Workstation copies the information from the DataBase into a comma separated text file. The file can be read by any spreadsheet application. It is often referred to as a .CSV or a .TXT file.

The file can be retrieved into any spreadsheet application. Use your spreadsheet program's instructions to transpose the information if it is not in a readable format.



Place an update label next to heading **Turning Autostop Off/on** on page 8-32 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

TURNING AUTOSTOP OFF/ON

1. Check that your controls and XB analysis are set up with the autostop options you want.
2. Select  to display the Run Configuration window.
3. If necessary, select the instrument you want.
4. Select the autostop options you want:
 - Controls
 - XB/XM
 - SlideMaker
 - No Match
 - No Read
 - Partial Aspiration
5. Select  to save the changes. The Workstation stops processing samples the next time it encounters the conditions you selected.



Place an update label next to heading **Online Help** on page xiv in the Introduction of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

USING HELP

Accessing Help

Your GEN•S System provides several methods for accessing information to help you find the information you need quickly. You can access Help by:

- Pressing 
- Selecting 
- Selecting  and then selecting an item on the screen
- Pressing  +  and then selecting an item on the screen
- Selecting an item, such as **Find Help**, from the Help menu.

Related Information

Many help topics contain hypertext lists of related information. If you see this graphic in the

header , you can select it to display a hypertext list of related information.

Jumping to Additional Information

Within a Help topic, there may be one or more jumps to other help topics. Jumps appear blue. Select the blue text with your light pen, mouse, or your finger (if you have a touch screen) to jump to additional information.

Many help topics also contain pop-up graphics. If you see this graphic , you can select it to display a pop-up graphic.

Tips



in a help is a special jump. If you select this graphic, a tip appears that can make your job easier.

Printing Help Topics

To print a Help topic you are currently viewing select .

To print a popup Help window, use your right mouse button to click inside the popup window, and then select Print Topic.

Note: Reference Information, Cleaning Procedure, and Replacing Procedure Help Topics that display full screen should be printed using Landscape Orientation.

Working with the Help Window

Drag the title bar to move the Help window. Use the border on the Help window to resize the window. Use the scroll bar to view information not visible in the Help window.

If the bottom of the scroll bar is covered by the command center, you can select Options Keep Help On Top On Top to uncover it.

If you need more information about using the Help system, press  when the Help window is open. The Windows NT Using Help window appears. You can use it to find out more about the help system.

Videos

Your GEN•S System provides online videos for selected cleaning, replacement and troubleshooting tasks. This information can assist you in performing these tasks. To see a video, your Help CD must be in the CD-ROM drive on the Workstation.

If you see this graphic , you can select it to jump to a video.



Place an update label next to heading 5.1, **Reviewing Sample Results** on page 5-1 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

VALIDATE SAMPLE

This button is only active when when you have results available for validation and you are reviewing samples from the Review List or the Completed List. . If any parameters are edited,



then save those results prior to selecting the validation icon.



Select to indicate that you have validated the sample and want it automatically printed and transmitted.



indicates the selected sample results have been validated.

Note: Validation from a Review List will also validate the results out of all other folders.

Required Access Level: Advanced Operator or Lab Administrator.



Place an update label next to heading 8.11, **Setting Up Rules for Flagging Sample Results** on page 8-15 of your GEN•S Operator's Guide, PN 4237222B, for the following new instrument function:

VALIDATION CODES AND MESSAGES

Validation messages appear in the footer of your GEN•S reports to indicate the validation status of the results. These messages are included with the standard data set transmitted to your information system. These messages include:

Sample Not Validated	Message displayed indicating that the results reported for the requested profile for the sample analyzed fails the AutoVerification criteria configured in the GEN•S Workstation.
Sample Validated	Message displayed after a Not Validated sample is manually validated at the GEN•S Workstation.
AutoValidated	Message displayed indicating that the results reported for the requested profile for the sample analyzed passes the AutoVerification criteria configured in the GEN•S Workstation.

Validation Codes also appear in the footer of your GEN•S reports next to the validation message. They are also transmitted to your information system if you have selected to Enable Validation Codes on the System Setup - Communications window. Each of the Validation Codes consists of a parameter block and a status indicator. The parameter blocks include:

Code	Parameter Block	Parameters Included
C	CBC parameter block	WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, and Research Parameters Pct, and PDW

D	Diff (differential) parameter block	NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA% and BA#
H	H&H parameter block	Hgb and Hct
R	Retic (reticulocyte) parameter block	Retic%, Retic#, and Research Parameters MRV, MSCV, IRF, HLR% and HLR#
W	WBC/Hgb/Plt parameter block	WBC, Hgb and Plt
4	CD4 Subset parameter block	CD4% and CD4#
8	CD8 Subset parameter block	CD8% and CD8#

Note: In order for the Research Parameters to be included in the parameter block, the Research Parameters must be unlocked and included in the report profile.

The status indicators that can exist for any parameter block are:

AV	AutoValidated
V	Validated (manual validation was performed at the GEN•S Workstation)
NV	Not Validated

All of the combinations that can exist are listed below. A minimum of one, up to a maximum of 7, parameter codes may exist for a sample. The number of parameter codes is dependent upon the report profile requested for a sample.

C NV	C V	C AV
D NV	D V	D AV
H NV	H V	H AV
R NV	R V	R AV
W NV	W V	W AV
4 NV	4 V	4 AV
8 NV	8 V	8 AV

A parameter block is present if at least one of the parameters in the block is included in the patient report.



Place an update label above heading **Light Pen** on page 1-3 of your GEN•S Operator's Guide, PN 4237222B, for the following additional information:

VERTICAL SCROLL BAR

Use the vertical scroll bar to move the text on the window up and down.

Scroll bars contain markers, called scroll boxes, that indicate the location of a window relative to the computer screen.

Do this

Select 

Select 

Click at the top of the scroll bar

Click at the bottom of the scroll bar

Drag 

To Do this

Scroll up one line at a time.

Scroll down one line at a time.

Jump towards the beginning of the list.

Jump towards the end of the list.

Move to an approximate location on the window.



Place an update label next to heading 7.9, **Viewing Database Count Information** on page 7-14 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

VIEWING DATABASE COUNT INFORMATION

1. Select  on the Command Center to access the Status application.

2. Select  to display the current database count information.

The system displays the number of completed records and the number of ToDo records in each database folder.

3. Select  to close the window.



Place an update label next to heading 3.6, **Xb Analysis** on page 3-10 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

XB ANALYSIS

Overview

XB Analysis is a quality-control method that monitors instrument performance (calibration) by tracking the MCV, MCH, and MCHC parameters of all patient samples. For more

information about XB Analysis, refer to the Operation Principles topic in the Reference Information section of the Help.

Using XB/XM

When using XB/XM Analysis, it is important to process samples randomly; for example, chemotherapy or neonate patient samples, if processed as a group, can cause XB/XM to be OUT.

When XB/XM Analysis is on, the Workstation compares the mean values with the target values and the percent limits. If the mean values are within the percent limits of the target values, then the XB/XM is IN.

Setup Options

When you set up XB/XM Analysis, you have options:

- You can specify that you want XB/XM to automatically stop processing on an instrument. Otherwise, XB/XM status appears in the XB/XM history log, and it is up to you to investigate it. You should investigate any batch that is out of the XB/XM limits.
- You can specify if you want to automatically print XB/XM Analysis information.

The options you specify are applied to the XB/XM Analysis of results the Workstation receives from all instruments attached to it.

Reviewing XB/XM Analysis Information

The Workstation displays the batch means for each parameter in graph form. The lines on the graph are from point to point, but when printed on the Graphic Printer, a horizontal bar represents each mean.

The Workstation determines if results should be included in a batch by considering several factors. The following factors cause results to be excluded from a batch:

- RBC value is less than 1.0×10^6
- Flow cell clog or partial aspiration
- Non-numeric value for MCV, MCH, and MCHC
- Non-numeric value for MCV and MCH and at least 25% of the samples have been excluded for MCHC, or manually excluded by the operator
- Non-numeric value for MCV and MCHC and at least 25% of the samples have been excluded for either MCHC or MCV, or manually excluded by the operator
- Non-numeric value for MCV and at least 25% of the samples have been excluded for MCV, or manually excluded by the operator
- Non-numeric value for MCH and MCHC and at least 25% of the samples have been excluded for either MCH or MCHC, or manually excluded by the operator
- Non-numeric value for MCV and at least 25% of the samples have been excluded for MCH, or manually excluded by the operator
- Non-numeric value for MCHC and at least 25% of the samples have been excluded for MCHC, or manually excluded by the operator

You can delete individual samples from the batch. The total number of deletes in a batch must not exceed 5 out of a batch size of 20 for XB; otherwise, the batch means calculation becomes invalid and is automatically removed from the Batch Means screen.



Place an update label next to heading **Setting Up Date and Time** on page 8-28 of your GEN•S Operator's Guide, PN 4237222B, for the following revised information:

YEAR 2000

All dates are stored numerically, in their entirety, including centuries.

Dates are displayed in two (2)-digit year format, except where ambiguity exists, such as date-of-birth which is displayed as four (4)-digit year format. The 4-digit date format also includes the date sample was drawn.

Dates edited through the User Interface or through the host are parsed with the following inference rule, as performed by Windows NT: two digit years ≤ 30 are part of century 2000, two digit years > 30 are part of century 1900.

The host transmission formats dates like the display, with 2-digit years for all dates except date of birth, which uses 4-digit years. Similarly, host requests for all dates must use the 2-digit format, except for date of birth which must use the 4-digit format and include date sample was drawn.

All aspects of the Workstation will continue to work properly through the millenium.



Place an update label next to Heading 1.7, **Calibrating CBC Parameters With Whole Blood** on page 1-8 of your GEN•S Special Procedures and Troubleshooting Manual, PN 4237223D, for the following revised information:

CALIBRATING CBC PARAMETERS WITH WHOLE BLOOD

1. Ensure the apertures are clean and the instrument is functioning properly.
2. Perform a 10-sample reproducibility study on the CBC parameters using the Automatic aspiration mode.
3. Perform a carryover study.
4. Obtain 20 normal, fresh whole-blood specimens. You need enough of each to cycle three samples on the GEN•S System and three samples on a reference instrument.
5. Using the same whole-blood specimens you used in step 4, obtain reference values from other instruments. The following methods are suggested:

WBC and RBC	COULTER ZBI analyzer used with ISOTON® II diluent and ZAP-OGLOBIN® II lytic reagent; use large volume dilutions made with calibrated glassware.
Hgb	Hemoglobincyanide spectrophotometric procedure that follows NCCLS Standard H15-A7. This method employs modified Drabkins (Ziljstra) Reagent and is referenced to NIST-certified filters and ICSH standards.
MCV	Packed cell volume measured by a hematocrit procedure that follows NCCLS Standard H7-A8. The PCV is not corrected for trapped plasma. MCV is calculated: $PCV/RBC \times 10$.
Plt	Phase-contrast microscopy.
MPV	Reference against latex particles.
6. Using the reference values, set up the CBC calibration information at the Workstation.
7. Run a prime sample. This sample will automatically be removed from statistics.
8. Cycle each of the 20 samples three consecutive times in CBC Automatic aspiration mode.
9. Review results on the Workstation Calibration window.
10. Adjust parameters as needed.
11. On the Command Center, select **AUTO ANALYSIS** as the processing control.
12. Verify calibration by cycling each level of COULTER 5C® cell control in Automatic aspiration mode.



Place an update label next to heading **1.6, Calibrating CBC Parameters With S-CAL® Calibrator** on page 1-4 of your GEN•S Special Procedures and Troubleshooting Manual, PN 4237223D, for the following revised information:

CALIBRATING CBC PARAMETERS WITH S-CAL® CALIBRATOR

1. Ensure the apertures are clean.
2. Ensure the instrument is functioning properly.
3. Perform a 10-sample reproducibility study on the CBC parameters using Automatic aspiration mode.
4. Perform carryover.
5. Prepare the instrument for calibration.
6. Set up the CBC calibration information at the Workstation.
7. Run S-CAL calibrator.
8. Review results on the Calibration window.
9. Adjust parameters as needed.
10. On the Command Center, select **AUTO ANALYSIS** as the processing control.
11. Verify calibration by cycling each level of COULTER 5C cell control in Automatic aspiration mode.



Place an update label next to heading **1.4, Performing Carryover Check** on page 1-3 of your GEN•S Special Procedures and Troubleshooting Manual, PN 4237223D, for the following revised information:

PERFORMING CARRYOVER CHECK

1. Ensure pneumatics are on.
2. Ensure the blood detector is disabled.
3. Ensure the mode of operation is set to CBC. You can perform carryover check using other operating modes, however the procedure will take longer and use excess reagents.
4. Ensure the number of aspirations per tube is set to 1.
5. If necessary, select the instrument name on the Command Center.
6. Select **CARRYOVER** as the processing control on the Command Center.



7. If necessary, select  on the Carryover window to clear out the values that appear on the results table.

Note: If you want to view the carryover results as the Workstation receives them, you can access the Carryover window (step 14) before proceeding. The background of the Carryover window, for the selected instrument, changes to the same background as the Command Center when you change the processing control to **CARRYOVER**.

8. Obtain a normal whole-blood specimen.
9. Separate the well-mixed normal whole-blood specimen into two 5 mL tubes.

10. Place the tubes into consecutive positions in a cassette.
11. Dispense 2 mL of diluent into three separate 5 mL tubes.
12. Place the three diluent tubes in the same cassette. Place the tubes after the whole-blood specimens.
13. Place the cassette in the loading bay. The instrument begins processing the cassette automatically.
14. On the Command Center, select **AUTO ANALYSIS** as the processing control if you are not continuing to either Reproducibility or Calibration.
15. Verify the carryover results.
16. Enable the blood detector.



Place an update label next to heading 1.2, **Performing Reproducibility Check -- CBC (N=10)** on page 1-1 of your GEN•S Special Procedures and Troubleshooting Manual, PN 4237223D, for the following revised information:

PERFORMING REPRODUCIBILITY CHECK -- CBC (N=10)

1. Ensure you have enough normal whole blood from a single donor for 11 cycles.
2. Ensure pneumatics are on.
3. Ensure the blood detector is enabled.
4. Ensure the number of aspirations per tube is set to 1.
5. Ensure the mode of operation is set to CBC. You can perform carryover check using other operating modes, however the procedure will take longer and use excess reagents.
6. If necessary, select the instrument name on the Command Center.
7. Select **REPRODUCIBILITY** as the processing control on the Command Center.



8. If necessary, select  on the Reproducibility window to clear out the values that appear on the results table.

Note: If you want to view the reproducibility results as the Workstation receives them, you can access the Reproducibility window (step 14) before proceeding. The background of the Reproducibility window, for the selected instrument, changes to the same background as the Command Center when you change the processing control to **REPRODUCIBILITY**.

9. Allocate approximately 1 ml of the well mixed normal whole blood sample into one tube.
10. Cycle one sample of normal whole blood in Automatic aspiration mode.

CAUTION Needle damage can occur if you pierce a specimen tube more than five times. Do not pierce a specimen tube more than five times.

11. Set the number of aspirations per tube to 5.
12. Separate the well-mixed normal whole-blood sample into two tubes.

13. Place the tubes into consecutive positions in a cassette and place the cassette in the loading bay. The system automatically begins processing the cassette. It pierces, aspirates, and analyzes the samples.
14. On the Command Center, select **AUTO ANALYSIS** as the processing control if you are not continuing to either Carryover or Calibration.
15. Review the reproducibility results.



Place an update label next to heading 4.6, **Enabling/disabling Blood Detector** on page 4-2 of your GEN•S Special Procedures and Troubleshooting Manual, PN 4237223D, for the following revised information:

ENABLING/DISABLING BLOOD DETECTOR

1. Go to the Analyzer screen.
2. Press **MAIN MENU**.
3. Press **SYSTEM CONFIGURATION**.
4. Press **BLOOD DETECTOR** until the appropriate setting appears.

Note: The system flags all parameters with a **P** (partial aspiration) when samples are analyzed with blood detectors disabled. P flagged control run results are automatically removed from statistical calculations, and there is no way to reintroduce the flagged runs into the calculations.

5. Press one of the following:

SYSTEM RUN To cycle samples.

RETURN To display the Analyzer **MAIN MENU** screen.



Place an update label next to heading 4.7, **Setting Up Analyzer Date And Time** on page 4-3 of your GEN•S Special Procedures and Troubleshooting Manual, PN 4237223D, for the following revised information:

SETTING UP ANALYZER DATE AND TIME

1. Go to the Analyzer screen.
2. Press **MAIN MENU**.
3. Press **ANALYZER FUNCTIONS**.
4. Press **DATE AND TIME**.
5. Press **SET DATE & TIME**.
6. Press the button for the setting you want to set up. Example: Press **MONTH**.
7. Go to the Diluter Keypad.

8. Press the value associated with the setting you want to specify. Each setting must be entered as a two-digit number. Example: Press   and then press .
9. Repeat steps 6 through 8 for each setting you want to specify.
10. Press one of the following:

SYSTEM RUN	To cycle samples.
RETURN	To display the DATE & TIME screen.
11. Read about GEN•S Year 2000 features.



Place an update label next to heading **F Set Up CBC Calibration Information at the Workstation** on page 1-6 of your GEN•S Special Procedures and Troubleshooting Manual, PN 4237223D, for the following revised information:

SETTING UP WORKSTATION CALIBRATION INFORMATION

Note: To perform this task, you must log on with a user name that was set up as an Advanced Operator or Lab Administrator. If you need to access this function, contact your laboratory administrator.

1. On the Command Center, select the instrument you want to calibrate if you have more than one instrument connected to your Workstation.
2. On the Command Center, select **CALIBRATION** as the processing control.
3. Select  to display the Quality Assurance application.
4. Select  to display the Calibration window.

Note: The background of the Calibration window, for the selected instrument, changes to the same background as the Command Center when you change the processing control to **CALIBRATION**.
5. If necessary, select the instrument you want to calibrate.
6. If necessary, select  to record the old calibration information in its history log and delete the information from the database. The values on the window change to 0.00.
7. If you have already set up calibration information, check that the appropriate lot number for calibration is selected; otherwise, set up new calibration information.

Note: Calibration runs will be rejected if the calibrator information has not been set up, or if the calibrator is expired. If expired, the Expiration field will be backlighted red, and a message 'Calibrator expired. No statistics will be calculated.' appears in the task bar.



Place an update label next to heading 5.1, **Overview** on page 5-1 of your GEN•S Special Procedures and Troubleshooting Manual, PN 4237223D, for the following revised information:

TROUBLESHOOTING OVERVIEW

Data Review

A review of instrument data, such as background, control and blood sample results, is helpful in detecting problems. Sometimes a questionable blood sample result is the only symptom of subtle reagent or pneumatic problems. In that case, you can use the questionable parameter result as a clue to the location of the malfunction.

Specimen-Related Problems

An instrument problem is differentiated from a specimen-related problem by running a control. If the control results are acceptable, the problem is probably specimen-related.

Instrument Problems

If the control results show similar problems, it indicates an instrument problem. The next step is to determine the subsystem (electronic, pneumatic/hydraulic, or reagent) causing the problem. Because it is easiest to detect a problem in the electronic subsystem and hardest to detect a problem in the reagent subsystem, the subsystems are usually checked in the following order: electronic, pneumatic/hydraulic, reagent.

Workstation Troubleshooting

If the Workstation encounters a problem, it tries to display a message. The message describes the problem and provides information about how to avoid or fix the problem. For best results, follow the instructions with the messages.

Some messages appear from the Windows NT™ operating system and other software packages that are included on your Workstation. Because these messages may not be logged by the Workstation and may not have online help available for them, it is important that you write these down and call your Coulter Representative.

If your Workstation is connected to a network, some messages may be caused by your network configuration. If you have a local network administrator or a Windows NT Administrator, contact your administrator prior to calling your Coulter Representative. Your administrator may be able to resolve the problem.

Note: During the course of testing the Workstation, specific intermittent problems have been reported and corrective actions have been determined. You may want to review the Problem List periodically to help avoid these problems.

Electronic Troubleshooting

Detecting a problem in the electronic subsystem--or eliminating the electronic subsystem as the source of the problem--is simplified by indicators and electronic tests.

Indicators

An indicator may inform you that a problem exists; it may also pinpoint the source of a problem. For example, the pneumatic light on the power supply appears red when a problem exists.

Electronic Tests

The ramp pulse, and precision pulse tests are electronic subsystem checks that the system performs without using the pneumatic/hydraulic and reagent subsystems. Therefore, when these test results are out of tolerance, the problem is in the electronic subsystem.

Correcting Electronic Problems

Although you may be able to correct minor problems, such as loose cables, most electronic problems require the assistance of your Coulter Representative.

Pneumatic/Hydraulic Troubleshooting

Most pneumatic/hydraulic problems are detected by observing the Diluter section in operation. When you identify a symptom of a malfunction, try to isolate the malfunction to the specific part of the cycle, for example, during preparation, counting, or cleanup. Then, try to isolate the malfunction to the specific components and tubing. Next, look for one of four possible problems--pinched tubing, plugs, leaks, or defective components.

Pinched Tubing

When tubing is pinched, flow is either restricted or stopped. Tubing most often pinches where it passes through, between, or around something, or where it attaches to a fitting. Examples: tubing passing through a pinch valve, around a panel, or between two hard objects.

Plug

A plug, like a pinch, restricts or stops a flow. A plug can be composed of liquid, salt, or debris. This type of problem may be hard to find because it often occurs inside other components. A plug can occur in tubing, in a fitting, at an aperture, or in a choke.

Plugs are most common in vacuum lines and waste paths that involve the use of fluids and air.

Leak

A leak allows fluid to escape before reaching its destination. If there is a leak in a pneumatic line, the pneumatic signal may fail to operate a component, such as a pinch valve, pump, or diluent dispenser. A leak generally occurs where one component attaches to another, such as where tubing attaches to a fitting, a housing, a pilot actuator, a pump, or the Blood Sampling Valve. Leaks can also be the result of cracks in components, such as pumps or glassware.

Defective Components

The interrelationship of components performing a pneumatic/hydraulic process can make it difficult to determine which component, if any, is defective. For example, if a pinch valve does not open, it is possible the pinch valve is defective. But it is also possible that the solenoid responsible for activating the pinch valve is defective.

Correcting Pneumatic/Hydraulic Problems

You can correct most pneumatic/hydraulic problems, including defective components.

Reagent Troubleshooting

A reagent problem can be as obvious as precipitate in the reagent tubing. In the less obvious cases, the most effective way of detecting a problem is by keeping a log of the lot numbers with the opening and expiration dates of the reagents in use, and knowing how each reagent affects the data. Refer to the labeling information with your reagents for details.

Correcting Reagent Problems

You can correct most reagent problems by changing the container of reagent and priming the instrument with the new reagent.



Place an update label next to heading 5.14, **Working With Electronic History Logbooks** on page 5-29 of your GEN•S Special Procedures and Troubleshooting Manual, PN 4237223D, for the following revised information:

WORKING WITH ELECTRONIC HISTORY LOGBOOKS



Select  on the Command Center to access the History Log Viewer application.

The tabs on this window present an organized view of the logbook information stored in the database. The Workstation logs messages automatically whenever you perform startup or shutdown. It logs messages when you process key events, such as changing reagent information or calibrating. If the Workstation encounters a problem, it also logs the problem.

Each time maintenance or corrective actions are performed on an instrument, the person performing the actions can update the Maintenance log with text describing the maintenance or corrective action performed.

Each log presents identification information, such as the date and time a message was logged, and system messages. You can access detailed descriptions and corrective actions for system messages from the Message List.

The most current message appears at the top of the window. . First-in events will be first out (removed) when the event log reaches its capacity. The first-in first-out functionality applies to all logs, not the entries within an individual log. An extremely active event log can cause items to be removed from other logs, e.g. the maintenance log. Periodic printout of the History Logs is suggested.

You can add comments to a logbook to help describe a problem or a corrective action you have taken. The Workstation saves the comments in the database along with the specific message.



Place an update label next to error message **Auto Slide** on page 7-34 of your SlideMaker Operator's Guide, PN 4237212A, for the following additional information:

AUTO CLEAR

The Analytical Station will perform an Auto Clear during any of the following conditions:

- **Full Clog.** When a Full Clog error condition occurs, the SlideMaker creates an Auto Slide during the same cycle. Auto Clear is displayed on the Analyzer and Diluter status lines.
- **Partial Clog.** When a Partial Clog error condition occurs, the SlideMaker creates an Auto Slide during the next sample because the Partial Clog condition lengthens the cycle subsequent to the cycle in which the error occurred. This makes it possible for an Auto Slide to then be created during a normal cycle. Auto Clear is displayed on the Analyzer and Diluter status lines.



Place an update label next to heading 5.4, **Checking Smear Quality** on page 5-10 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

CHECKING SMEAR QUALITY

Smear quality may be affected by several factors, including the quality of the glass slide, the condition of the blood specimen, and the instrument's performance. A discussion of these factors follows.

- **Slide quality:** BECKMAN COULTER slides have been manufactured to maximize compatibility with your SlideMaker. They are double-washed to ensure cleanliness and specially packaged to reduce humidity and debris. Our slides have also been designed with strategically placed frosted areas to help prevent multiple slides from sticking together. But because excessive humidity could cause even these slides to stick together, you should load the cassettes with only those slides needed for one day of SlideMaker operation. Be sure to store the slides in a low-humidity environment and bring them to ambient room temperature before you open the slide package. You should also take precaution to avoid touching the smearing surface of the slides when you are loading slides into the cassettes to avoid fingerprints, which could cause vacuoles in your smears. Lesser quality slides could result in excessive debris, multiple streaks, irregular vacuoles, or an increase in slide jams.
- **Specimen condition:** Morphological artifacts on the smear could be the result of prolonged storage or inadequate mixing.
- **Instrument performance:** Mechanical problems could result in smears that are too short, too thick, or too thin. Streaks on the smears could also be an indication of an instrument problem.
- **Discard any slides that do not have labels on them after processing by the SlideMaker.**
- **Blood collection and handling techniques as well as film fixation and staining methods,** while generally controllable when closely monitored, may be a source of random variability.

- While the number of cells counted is not statistically representative of the sample leukocyte population, evaluation errors can be reduced by increasing the number of cells counted on a film as well as increasing the number of slides read on a particular sample.
- When preparing manual blood films, it is advisable to use a spreader slide which is narrower than the film slide or one that has beveled corners in order to produce a film with lateral edges that can be evaluated.
 - Spreader slides should have a polished edge to minimize leukocyte distribution errors.
 - Delays in the spreading of the blood drop will result in poor leukocyte distribution.
 - Poor cell distribution and reproducibility results if the forward stroke of the spreader slide is too slow.
- Laboratory conditions, especially extremes in humidity and temperature adversely affect slide shelf life and blood film quality.
- Sample characteristics such as low hematocrits, viscosity, cell type and size, and sample age are considered uncontrollable but significant sources of variability.

Characteristics of a Good Smear

- The film should show a gradual transition in thickness from the thick to thin areas. The far end being void of grainy streaks, troughs or ridges.
- The field of examination should range from an area where there is 50% overlap of erythrocytes to a region where erythrocytes show a tendency toward linear orientation.

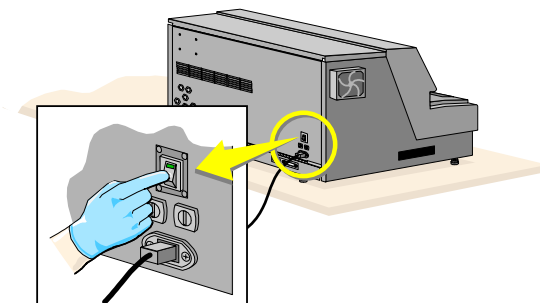


Place an update label next to heading **Cleaning The Dispense Probe And Rinse Cup** on page 6-7 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

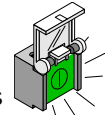
CLEANING THE DISPENSE PROBE AND RINSE CUP

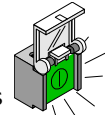
Procedure

CAUTION Possible biohazardous condition. Handle with care. Avoid skin puncture. Dispose of all contaminated disposable cleaning materials and broken slides (sharps) in accordance with your local regulations and acceptable laboratory practices.

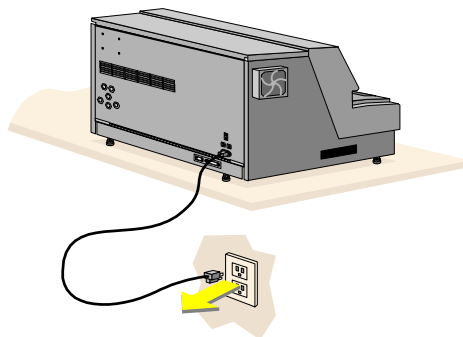


1. Use a cleaning solution capable of inactivating the Human Immunodeficiency Virus (HIV) and Hepatitis B (HBV). To make an acceptable cleaning (bleach) solution, mix:
 - Four parts water.
 - One part high-quality, fragrance-free bleach (5% sodium hypochlorite - available chlorine).



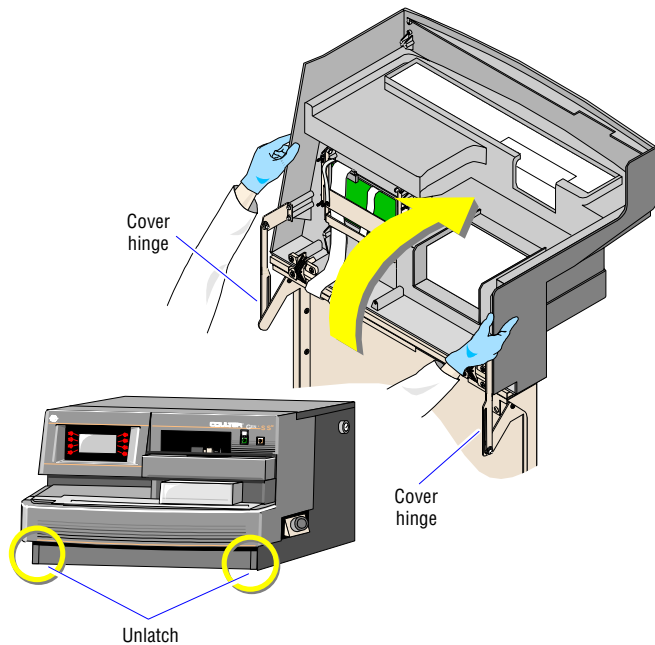
2. Press  to turn off the SlideMaker.
3. Turn off the power.

WARNING Risk of personal injury. A shock hazard exists if the power cord is connected. Unplug the primary power cord before performing these procedures.



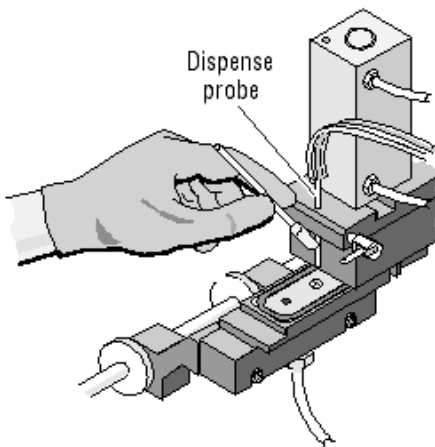
4. Unplug the power cord.

WARNING Risk of personal injury. Injury could result if the cover hinge is not engaged. Be sure to engage one of the cover hinges.



5. Using both hands, raise the cover to release the lower latches.
6. Push the cover all the way back and then slightly forward to engage at least one of the hinges. (Note: If you engage both hinges, it will be more difficult to close the cover.)

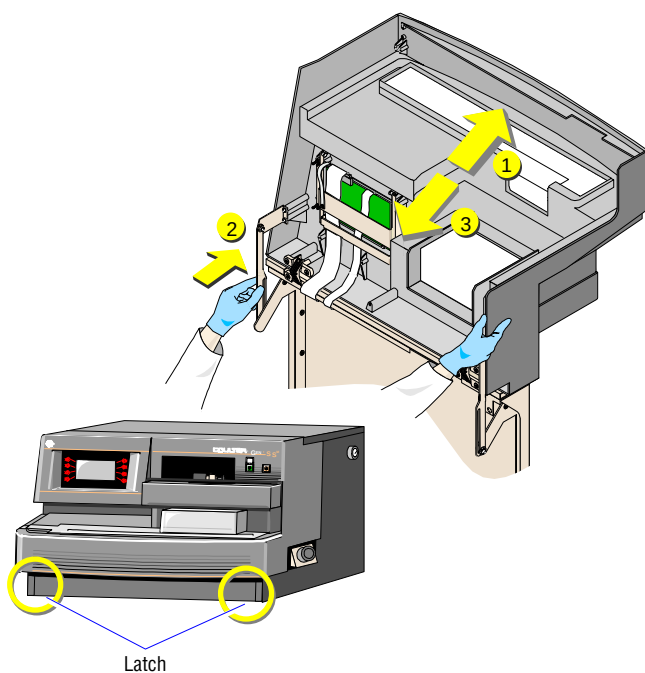
WARNING Risk of injury from movable part. Be careful when working with movable parts



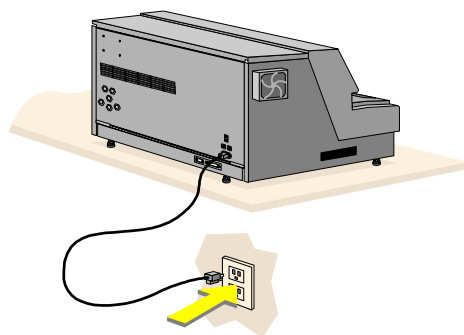
7. If necessary, manually move the smear truck and shuttle so they do not obstruct your view of the dispense probe.
8. Clean the dispense probe and rinse cup with a cotton swab moistened with the bleach solution.
9. Dip another cotton swab in water and wipe the same area.
10. Using a squeeze bottle, rinse with a small amount of bleach liquid any remaining particulate matter from the dispense probe and rinse cup. Direct the liquid stream into the rinse cup opening so as not to spill bleach inside the instrument. Dry gauze pads can be used to absorb excess liquid.

11. Access the sample probe by releasing the locking mechanism for the sample probe. Pull out on the handle-like device located at the front of the sample probe housing while simultaneously grasping the sample probe at the probe/tubing junction and pulling upward.
12. Use a gauze square moistened in bleach to remove any blood residue from the external surfaces of the sample probe.
13. Inspect the sample probe orifice for any obstructions and, if necessary, remove the instrument sample tubing from the probe. Clear the sample probe with several forceful jets of bleach from the plastic squeeze bottle.
14. Rinse any remaining bleach from the sample probe with ISOTON® and replace the sample probe tubing, if removed.
15. Return the sample probe to the sample probe housing by pulling out the handle-like device to allow minimal entry of the sample probe into the housing. Once entry has been achieved, gentle downward force will allow the probe to travel to its locked position. A small "click" may be audible upon securing the sample probe in the proper locked position.

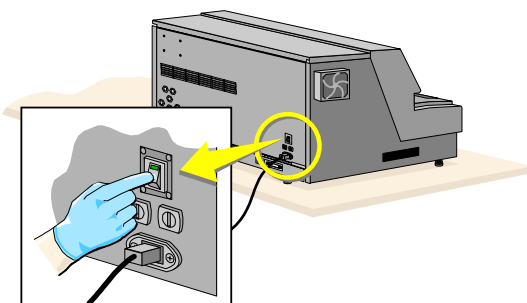
WARNING Risk of personal injury. Injury could result if the cover falls while the hinges are being disengaged. Be sure to steady the cover with one hand while disengaging the hinge with the other hand.



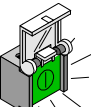
16. Close the cover.
 - a. Move the cover back slightly.
 - b. Disengage the hinges on both sides.
 - c. Close the cover, ensuring the lower latches are engaged.



17. Plug in the power cord.



18. Turn on the power.

19. Press  to turn on the SlideMaker.



Place an update label above heading 5.5, **Shutdown** on page 5-4 of your SlideMaker Operator's Guide, PN 4237212A, for the following additional information:

DEFINE SMEAR SPEED OVERVIEW

The DEFINE SMEAR SPEED screen allows for modification of speed profiles and wicking times used by the spreader slides to produce blood films. If no previous modifications exist, pointers for each selectable parameter are set initially at mid scale (Position 5).

Spreader slide speed and delay ratio of the spreader is critical to the length, shape and cell density of a whole blood film. Spreader speed and delay also affects cell distribution and the overall quality of whole blood films.

The GEN•S SlideMaker has embedded within its special function software menu an option (DEFINE SMEAR SPEED screen) that enables the laboratory to vary the speed used by spreader slides to process blood films. The speed functions are used to correct blood films that are either too long or too short due to extremes in sample viscosity. These functions enable the laboratory to customize the film profile to meet their own requirements. The wick time function is useful in compensating for variability in lot-to-lot slide surface wettability. By delaying the forward motion of the spreader slide when in the wicking position, more favorable square-end profiles are provided. Duplicate slides, due to narrow blood films, are minimized by allowing the blood droplet to move along the entire forward edge of the slide.

Wettability: The ability of any solid surface to be wetted when in contact with a liquid. Wettability affects the smear quality:

- Dirty slides concentrate the blood droplet in one location resulting in a poor quality smear.
- Clean slides allow for the blood droplet to disperse evenly across the slide providing for a good quality smear.



Place an update label above heading 5.5, **Shutdown** on page 5-4 of your SlideMaker Operator's Guide, PN 4237212A, for the following additional information:

DEFINE SMEAR SPEED

1. Ensure:
 - SlideMaker is ready to make smears.
 - GEN•S System is ready to process samples.
2. Press **EXIT** on the SlideMaker display until you reach the MAIN MENU screen.
3. Press **SPECIAL FUNCTIONS**.
4. Press **DEFINE SMEAR SPEED**.

5. The following options are available from the DEFINE SMEAR SPEED screen:

SPEED 1	The Speed function allows the blood film to be lengthened or shortened.
SPEED 2	The Default speed function is used in conjunction with the Speed function and allows for blood film length adjustments to be made on samples having extremely high or low viscosities.
Wick	The Wick function is used to compensate for variations in slide surface wettability.
Save Value	The SAVE VALUE option saves any modifications to the speed and wick positions.
Exit	This option returns you to the RUN MODE screen.
6. Press the arrow keys ↓ ↑ to either decrease (lengthen film) or increase (shorten film) the Speed and Default speed factors.
7. Press the arrow keys ↓ ↑ to either decrease (shorten wicking) or increase (lengthen wicking) the Wick ratio.
8. Press **SAVE VALUE** to use the new speed and wick settings in the next processed sample.
9. Press **EXIT** to return to the RUN MODE screen.



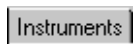
Place an update label next to heading **Ensuring The Slidemaker Is Enabled** on page 5-3 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

ENSURING THE SLIDEMAKER IS ENABLED

In order for SlideMaker to be enabled, the Communications window of System Setup and the SlideMaker tab from the Run Configuration window must be properly configured.

System Setup – [Communications]



1. Select  to display the Communications window.
2. Select  to display the settings for the instruments attached to your Workstation.
3. Select the instrument with the SlideMaker attached.
4. Check that ☒ appears in the SlideMaker field.
5. Check that the serial number for the SlideMaker appears on the window.

Run Configuration – SlideMaker tab



1. Select  to display the Run Configuration window.
2. Check that ☒ appears in the SlideMaker field.
3. Select the preferred Automatic Output option for controls and samples.



Place an update label next to step 6 on page 5-2 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

LABORATORY ID

Text entry field for lines 2 through 7 on the label.

Note: Do not use the “?” character. It is a reserved character and will not print on the label.



Place an update label next to heading **Main Menu Screen** on page 5-1 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

MAIN MENU SCREEN (SLIDEMAKER)

Use this screen to access the functions you want to perform.

Routine Functions

Press This Menu Item

To

Pneumatic/Power
Supplies

View SlideMaker pneumatic and power supply levels.

Advance Basket

Advance a slide basket one basket position.

Unlock Cassette

Release the slide cassette.

Lock Cassette

Lock the slide cassette.

Printer Label Functions

Access functions to:

Decrease printer intensity.

Increase printer intensity.

Save printer intensity.

System Settings

View SlideMaker settings, such as the slide counter and cycle counter.

Routine Fluidics

Access functions to:

Prime Reagent Reservoirs.

Drain the SlideMaker.

Rinse the SlideMaker vacuum accumulator.

Prime the SlideMaker.

Start up the SlideMaker.

Shut down the SlideMaker.

Special Functions

Press This Menu Item

To

Define Smear Speed

Modify speed and wicking times used by the spreader slides.

Dryer Temperature

View the dryer temperature status.

Display Test

Test the SlideMaker display screen.

Dryer Function Test

Access functions to test the dryer and heater motors.

Reboot Printer

Reinitialize the SlideMaker printer.

Sensor Status

Displays the state (on/off) of each sensor.

Keypad Test

Test the SlideMaker keypad.



Place an update label next to heading **Special Functions** on page 5-1 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

SENSOR STATUS

The Sensor Status screen displays each sensor and its state (on/off). Navigation through the table is facilitated by the directional arrow keys. The name of each sensor is displayed in the lower left-hand corner of the SlideMaker screen. Typically, this display is used for troubleshooting by Coulter Service personnel.



Place an update label next to heading **5.2, SlideMaker Setup** on page 5-2 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

SETTING UP WHEN TO MAKE A SLIDE

1. Select  to display the Run Configuration window.
2. Select  .
Note: These selections are currently available only for samples that are processed in CBC or CBC/Diff mode.
3. Ensure decision criteria is enabled then select the flag type you want to use to determine when a slide is made.
Note: Select **SlideMaker Decision Rules Only** and enable decision criteria if you want to use only your decision rules to determine when a slide is made. Select **Specific Flags** if you want to make slides on specific conditions that cause a sample result to be sent - slides will also be made using the SlideMaker Decision Rules.
4. Select  to save the changes.



Place an update label next to heading **7.1, Overview** on page 7-1 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

TROUBLESHOOTING OVERVIEW (SLIDEMAKER)

Overview

Slide quality is often the source of problems with the SlideMaker. When slides jam frequently on the SlideMaker, check your slides. Checking the SlideMaker for possible slide jams is also helpful in detecting problems. Make sure to check the:

- Slide cassette
- Slide Ejector module
- Shuttle
- Dryer

- Smear truck
- Slide platen and elevator
- Pusher bars

Smear quality can be affected in several ways.

- Cleaning the Dispense Probe and Rinse Cup

The SlideMaker screen allows you to perform several troubleshooting and general functions:

- Slide label problems
 - Increasing printer label intensity
 - Decreasing printer label intensity
 - Rebooting the printer
 - Saving printer label intensity
 - Testing label printing
- Fluidic problems
 - Draining the SlideMaker
 - Rinsing the SlideMaker vacuum accumulator
 - Priming/Backwashing the SlideMaker
 - Priming reagent reservoirs
 - Starting up the SlideMaker
 - Shutting down the SlideMaker
- Advancing a slide basket
- Checking pneumatic/power supplies
- Testing SlideMaker Keypad
- Testing SlideMaker Display

If you suspect a problem in any of these areas, you can attempt to perform these functions before calling your Coulter Representative. If requested to do so by a Coulter Representative, you can also use the reset switch on the SlideMaker.



Place an update label next to heading **Viewing Slidemaker Settings** on page 7-30 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

VIEWING SLIDEMAKER SETTINGS

Procedure

1. Ensure:
 - SlideMaker is either making or ready to make smears.
 - GEN•S System is either processing or ready to process samples.

2. Press **EXIT** to access the MAIN MENU screen.
3. Press **ROUTINE FUNCTIONS**.
4. Press **SYSTEM SETTINGS**. The SYSTEM SETTINGS screen appears as follows.

Gen•S SYSTEM SETTINGS	
PROCESSOR A VERSION	*****
PROCESSOR B VERSION	*****
TABLE A VERSION	*****
TABLE B VERSION	*****
BOOT A VERSION	*****
BOOT B VERSION	*****
PRINTER REVISION	*****
SLIDE COUNTER	*****
CYCLE COUNTER	*****
EXIT	

- SlideMaker software version for each microprocessor
 - SlideMaker table versions for fluidics and screen display
 - SlideMaker printer revision
 - Slide counter - initialized to one, increments by one for each slide prepared; cannot be reset
 - Cycle counter - initialized to one, increments by one each blood that is aspirated; cannot be reset
 - Unit serial number - from Workstation
5. Press **EXIT** until you reach the MAIN MENU screen.
 6. Press **RUN MODE** to return to the RUN MODE screen.



Place an update label next to heading **References** on page References-1 of your SlideMaker Operator's Guide, PN 4237212A, for the following revised information:

REFERENCES--SLIDEMAKER

1. Lewis SM. Blood film evaluations as a quality control activity. Clinical and Laboratory Haematology. Koepke JA and England JM, eds. Blackwell Scientific Publications, London, 1990.
2. NCCLS document. Reference leukocyte differential count (proportional) and evaluation of instrumental methods. National Committee for Clinical Laboratory Standards. Villanova, PA, 1992.
3. Rumke, C.L. The Statistically Expected Variability in Differential Leukocyte Counting. Differential Leukocyte Counting, John A. Koepke, ed. Conference of the College of American Pathologists, Aspen, 1977.
4. NCCLS document H20-A. Approved Standard for the Evaluation of the Differential Cell Count. National Committee for Clinical Laboratory Standards. Villanova, PA, 1992.

5. International Standard ISO 8037/1, Optics and Optical Instruments-Microscope-Slides-Part 1: Dimensions, Optical Properties and Markings.
6. NCCLS document H20-A, Volume 12, Number 1. *Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental methods*. Approved Standard March 1992, Section 3.1.2.
7. Steine-Martin, E. Anne, *Causes for Poor Leukocyte Distribution in Manual Spreader Slide Blood Films*, Am Jour. of Med. Tech. 46-9-80 pg. 624-632.



Place an update label next to heading **Pneumatic/hydraulic Tubing Connections** on page 2-4 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

PNEUMATIC/HYDRAULIC TUBING CONNECTIONS

CAUTION Possible reagent siphoning effect and priming problems can occur if a reagent container is placed above the level of the Analyzer. Do not place reagent containers above the level of the Analyzer.

IMPORTANT Placing Reagent Paks in any location other than on the counter next to the instrument may cause erroneous results.

Figure 2.3 shows the tubing connections between the Diluter and the:

- Reagent containers
- Waste container
- Power Supply pressure and vacuum supplies.

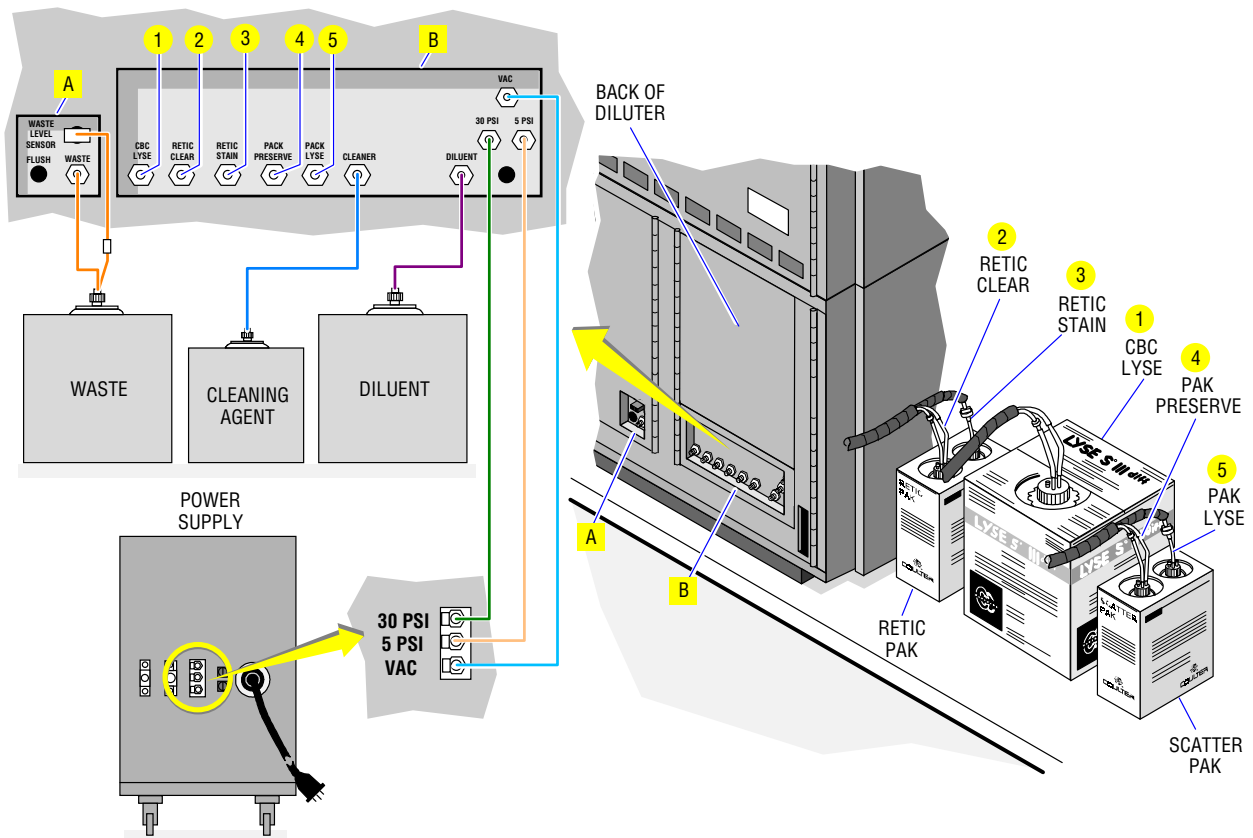


Figure 2.3 Pneumatic/Hydraulic Connections



Place an update label next to heading **Loading Specimens** on page 3-2 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

LOADING SPECIMENS

1. The operator places specimen tubes, which can be identified by bar-code labels, into cassettes. Each cassette and the tube positions in the cassette are identified by bar-code labels.
2. You can load up to 12 standard or Hemogard cassettes with 144 samples into the loading bay at one time. Figure 3.2 shows the loading bay filled with cassettes.



Place an update label next to heading **Aspiration** on page 3-4 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

ASPIRATION

At the sampling station, after the cap is pierced:

1. A pump draws a maximum of 300 μ L of sample through the needle and through the Blood Sampling Valve (BSV).
2. The blood detectors monitor the passage of sample through the BSV and aspiration lines.
3. The needle is withdrawn and the sample tube is resealed in the cassette.

Delivery

CBC

After the sample is aspirated:

- The center section of the BSV rotates and segments the sample into two separate volumes.
- Beginning a few seconds before the delivery of the dilutions to the appropriate baths, 5 psi of pressure is sent to the WBC bath. This pressure allows drainage of any residual liquid in the WBC bath, thus preventing carryover.
- The pressure continues during delivery and forms bubbles that mix each cell suspension before sensing begins.
- At the beginning of the delivery, any residual rinse in the Hgb cuvette drains into the waste chamber and the waste chamber drains.
- Diluent from the diluent dispensers drives the separated volumes of sample from the BSV to the baths.
- One volume of sample, 1.6 μ L, is delivered with 10 mL of diluent to the RBC bath. This dilution is used for RBC/Plt counting and MCV/Plt sizing.
- The other volume, 28 μ L, is delivered with 6 mL of diluent to the WBC bath. This dilution is used to count WBC and develop Hgb.
- During delivery to the WBC bath, 1 mL of lytic reagent is added to the dilution to lyse the red cells and convert Hgb.

- At the same time the lytic reagent is dispensed, 5 mL of diluent from the backwash tank is transferred into the Hgb cuvette for the Hgb blank reading.
- The final dilution in the WBC bath is 1 part whole blood in a total volume of 251 parts. The final dilution in the RBC bath is 1 part whole blood in a total volume of 6250 parts.
- The vent section of the piercing needle is rinsed, then dried by high vacuum.
- The center section of the BSV returns to the aspirate position.

Differential (Diff) and Retic

At the same time as the segmented parts of the sample are being delivered to the baths, the Diff and Retic segmenting modules segment additional 31 μ L samples of the blood for analysis.

- For the WBC differential, the sample and approximately 0.506 mL of heated Diff lytic reagent are delivered to the mixing chamber, which agitates to mix them thoroughly.
- During the mixing process, approximately 0.2 mL of Diff preservative enters the mixing chamber to preserve the leukocyte populations, and the instrument initiates the sheath stream of diluent in the triple-transducer flow cell.
- For the Retic analysis, the sample and approximately 166 μ L of Retic stain are delivered to the Stain chamber, where they are mixed, heated and incubated for 31 seconds.

A 2- μ L segment of the stain/blood mixture and 2.00 mL of heated or cooled Retic clearing solution are delivered to the Retic chamber, where they are mixed and incubated for 25 seconds.

The sample line between the Retic chamber and the flow cell is primed with the stain/blood/clearing solution before cell counting begins. After the sample line is primed, the flow cell is cleaned and primed with diluent, and the sheath stream of diluent begins.

For both the WBC differential and the Retic analysis, the instrument injects the sample into the center of the sheath stream and activates the flow cell aperture current. The laminar flow guides the sample through the center of the flow cell aperture; the sheath stream on the exit side of the flow cell aperture prevents the sample's cells from re-entering the aperture.

CBC Sensing System

Vacuum, equal to 6 in. of mercury, draws a precise volume of suspension from each bath through the three apertures. At the same time, sweep flow is drawn behind the RBC apertures to prevent cells from re-entering the sensing zone.

When the vacuum starts to draw the suspension, current is supplied to the electrode. The electrical path allows sensing of the number and volume of each cell pulled through the apertures.

While the sample in each bath is sensed, the photometer reads the Hgb-blank and the Analyzer retains this reference voltage.



Place an update label next to heading **Hemoglobin (Hgb) Concentration** on page 3-14 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

HEMOGLOBIN (Hgb) CONCENTRATION

The transmittance of light (525 nm wavelength) through the lysed WBC solution in the hemoglobin cuvette is compared to the transmittance of the same light through a reagent blank. The system converts this ratio to an Hgb value in g/dL using a calibration factor.

Weight (mass) of hemoglobin determined from the degree of absorbance found through photocurrent transmittance is:

$$\text{HGB (g / dL)} = \text{Constant} \times \log_{10} \frac{\text{Reference \%T}}{\text{Sample \%T}}$$



Place an update label next to heading **Sample Stability** on page 4-1 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

SAMPLE STABILITY

Reticulocyte Parameters

- Stored at room temperature (23.9°C or 75°F), up to 24 hours after collection
- Stored between 2 and 8°C (35.6 and 46.4°F), up to 72 hours after collection



Place an update label next to heading **Throughput, Automatic Mode** on page 4-2 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

THROUGHPUT, AUTOMATIC MODE

Typical throughput performance is described as "average" for samples exhibiting parameter levels within the normal range, and "maximum" for samples with elevated parameter levels. Approximate throughput performance data, not including sample preparation, is:

	Average	Maximum
CBC	105	120
CBC/Diff	105	110
CBC/Diff/Retic	50	55

The GEN•S System throughput in CBC and CBC/Diff mode is slightly lower when interfaced with the GEN•S SlideMaker. Throughput requirements are based on the sample criteria in Table 4.1.

Table 4.1 Throughput Sample Criteria

Parameter	RETIC modes	CBC	CBC/DIFF
WBC	N/A	> 7.0 x 10 ³ /μL	> 7.0 x 10 ³ /μL
RBC	> 5.0 x 10 ⁶ /μL	> 5.0 x 10 ⁶ /μL	> 5.0 x 10 ⁶ /μL
Plt	N/A	> 300.0 x 10 ³ /μL	> 300.0 x 10 ³ /μL



Place an update label next to heading **WBC Differential Parameters, 5C Cell Control** on page 4-8 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

WBC DIFFERENTIAL PARAMETERS, 5C CELL CONTROL

Table 4.9 shows the WBC Differential results for 31 replicate determinations of 5C Normal cell control, 5C Abnormal I cell control and 5C Abnormal II cell control..

Table 4.9 WBC Differential Precision, 5C Cell Control

Parameter	5C Normal Cell Control		5C Abnormal I Cell Control		5C Abnormal II Cell Control	
	Mean	2SD	Mean	2SD	Mean	2SD
NE%	54.04	1.08	65.32	1.13	42.95	2.06
LY%	29.28	0.40	13.64	0.66	46.41	2.23
MO%	8.23	0.86	14.88	0.80	5.95	0.55
EO%	8.32	0.73	6.09	0.58	4.41	0.60
BA%	0.13	0.11	0.07	0.07	0.28	0.26



Place an update label next to heading **Reticulocytes, Retic-C Cell Control** on page 4-8 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

RETICULOCYTES, RETIC-C CELL CONTROL

Table 4.10 shows Retic results for 31 replicate determinations of Retic-C Cell Control.

Table 4.10 Reticulocytes Precision, Retic-C Cell Control

	Level I	Level II	Level III
Mean	0.978	2.901	9.807
SD	0.114	0.097	0.267
CV%	11.652	3.332	2.724



Place an update label next to heading **WBC Differential, Whole Blood** on page 4-9 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

WBC DIFFERENTIAL, WHOLE BLOOD

Table 4.12 shows the WBC Differential results for 31 replicate determinations of whole blood in K3EDTA, Automatic Mode.

Table 4.12 WBC Differential Precision, Whole Blood

Parameter	Mean	2 SD
NE%	51.19	1.18
LY%	37.06	1.08

MO%	8.14	0.79
EO%	3.25	0.41
BA%	0.35	0.13



Place an update label next to heading **Reticulocyte Precision, Whole Blood** on page 4-9 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

RETICULOCYTE PRECISION, WHOLE BLOOD

The RET% results for 31 replicate determinations of whole blood in K3EDTA, Automatic Mode are:

Mean	1.121
1 SD	0.0878
CV%	7.838



Place an update label next to heading **Accuracy of the Differential Parameters** on page 4-10 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

ACCURACY OF THE DIFFERENTIAL PARAMETERS

Accuracy for the Differential parameters was defined as the agreement between the GEN•S System and NCCLS H20-A Reference Methodology for the five-part differential parameters. Estimates of agreement were made by pair-difference analysis. The magnitude of the Mean Difference expresses accuracy; see Table 4.14.

Table 4.14 Diff Accuracy Analysis: Compared Samples, Auto Mode

Parameter	Units	N	Population Minimum	Population Maximum	Mean Difference	SD
NE	%	193	7.25	92.00	-0.69	3.15
LY	%	193	3.00	90.50	-1.00	3.09
MO	%	193	1.25	18.25	1.70	1.70
EO	%	193	0.00	13.50	0.13	1.01
BA	%	193	0.00	4.75	-0.14	0.47



Place an update label next to heading **Accuracy Of Reticulocytes** on page 4-11 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

ACCURACY OF RETICULOCYTES

Accuracy for Reticulocyte parameters was defined as the agreement between the GEN•S System with the comparator Flow Cytometry instrument and NCCLS H16-P manual reference methodology. Estimates of agreement were made by pair-difference analysis. The magnitude of the Mean Difference and SD of the difference expresses accuracy. See Table 4.15.

Table 4.15 Retic Accuracy Analysis: Compared Samples, Auto Mode

Parameter	Units	N	Population Minimum	Population Maximum	Mean Difference	SD
RET*	%	262	0.00	18.50	-0.27	0.85
RET**	%	261	0.00	13.40	-0.45	0.62

* NCCLS

** Flow Cytometer



Place an update label next to **Table 4.17** on page 4-12 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

TABLE 4.17

Table 4.17 shows the clinical sensitivity for morphologic abnormalities.

Table 4.17 Clinical Sensitivity for Morphologic Abnormals, Default Differential Flagging Preferences*

	Positive (Abnormal)		Negative (Normal)		Total	
	GEN•S System A	GEN•S System B	GEN•S System A	GEN•S System B	GEN•S System A	GEN•S System B
Reference Positive (Abnormal)	38 (TP)	38 (TP)	13 (FN)	11 (FN)	51	51
Reference Negative (Normal)	13 (FP)	20 (FP)	202 (TN)	195 (TN)	215	215
Total	51	60	215	206	266	266

*Instrument Positive selections = Blast, Variant LY, NRBC, Imm NE 1, and Imm NE 2 at mid-level.



Place an update label next to heading **Summary** on page 4-13 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

SUMMARY

	GEN•S System A	GEN•S System B	Calculation
Agreement (Efficiency)	90.23	88.35	$[(TP+TN)/TOTAL] \times 100$
FP Ratio (NCCLS)	6.05	9.30	$[FP/(FP+TN)] \times 100$
FN Ratio (NCCLS)	25.49	21.57	$[FN/(FN+TP)] \times 100$
% FP (% of Total)	4.89	7.52	$[FP/Total\ Number] \times 100$
% FN (% of Total)	4.89	4.14	$[FN/Total\ Number] \times 100$
Prevalence: % Normal	215/280 (76.79%)	215/280 (76.79%)	$[REF.\ NORM./TOTAL] \times 100$
Prevalence: % Abnormal	51/280 (18.21%)	51/280 (18.21%)*	$[REF.\ ABN./TOTAL] \times 100$

**Prevalence includes non-reportable results (for example, flow cell clog, Verify Diff suspect flag).



Place an update label next to heading **Individual Flagging Performance** on page 4-13 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

INDIVIDUAL FLAGGING PERFORMANCE

GEN•S Workstation Software Version 2B1 allows individual selection of the following flags at three levels (low, mid, high): Blast, Variant LY, NRBC, Imm NE 1, and Imm NE 2. The display, printing, and transmission of Imm NE 1 can be enabled or disabled.

Individual flagging performance for GEN•S system A and B is shown below, based on reference positive criteria described in NCCLS H20-A. This data was obtained from a database of approximately 2,685 clinical specimens.

	Low	Mid	High
BLAST			
Agreement (Efficiency)	89.80	88.31	86.29
FP Ratio (NCCLS)	9.89	11.59	13.72
FN Ratio (NCCLS)	15.54	13.51	13.51
%FP (% of Total)	9.35	10.95	12.96
%FN (% of Total)	0.86	0.74	0.74
VARIANT LY			
Agreement (Efficiency)	96.35	95.97	91.21
FP Ratio (NCCLS)	2.56	3.59	6.55
FN Ratio (NCCLS)	47.69	38.46	59.19

%FP (% of Total)	2.50	3.50	5.88
%FN (% of Total)	1.15	0.93	0.60

NRBC

Agreement (Efficiency)	95.16	91.10	75.75
FP Ratio (NCCLS)	3.43	8.49	25.42
FN Ratio (NCCLS)	28.29	15.79	4.61
%FP (% of Total)	3.24	8.01	23.99
%FN (% of Total)	1.60	0.89	0.26

Imm NE 1

Agreement (Efficiency)	82.12	81.56	80.82
FP Ratio (NCCLS)	17.50	18.40	19.43
FN Ratio (NCCLS)	19.73	18.63	17.96
%FP (% of Total)	14.56	15.31	16.16
%FN (% of Total)	3.31	3.13	3.02

Imm NE 2

Agreement (Efficiency)	88.19	86.59	85.47
FP Ratio (NCCLS)	6.76	9.52	11.98
FN Ratio (NCCLS)	47.59	40.96	32.53
%FP (% of Total)	5.92	8.34	10.50
%FN (% of Total)	5.88	5.07	4.02



Place an update label next to heading **Reference Ranges** on page 4-14 of your GEN•S Reference Manual, PN 4237221B, for the following revised information:

REFERENCE RANGES

A Normal Range study was conducted to assess the Reference Ranges for the GEN•S System. Whole-blood samples were collected from 240 donors (equal numbers of males and females). The selection of donors was consistent with guidelines stated in NCCLS, C28-A. See Table 4.18. Normal Population Study

Table 4.18 Normal Population Study

Parameter	Units	Gender	Mean	95% Confidence Low Limit	95% Confidence High Limit
WBC	x 10 ³ cells/μL	M/F	6.11	3.58	11.07
RBC	x 10 ⁶ cells/μL	F	4.241	3.691	4.877
RBC	x 10 ⁶ cells/μL	M	4.829	4.270	5.493
Hgb	g/dL	F	12.82	11.35	14.35

Hgb	g/dL	M	14.56	12.92	16.12
Hct	Ratio	F	37.10	33.27	41.39
Hct	Ratio	M	42.08	37.65	46.48
MCV	fL	M/F	87.36	79.30	94.80
MCH	pg	M/F	30.23	26.80	33.16
MCHC	g/dL	M/F	34.56	33.51	35.54
RDW	%	M/F	13.16	11.99	15.14
Plt	x 10 ³ cells/ μ L	M/F	242.16	165.40	352.90
MPV	fL	M/F	8.87	7.51	10.65
NE	%	M/F	58.25	43.33	71.94
LY	%	M/F	30.07	16.75	43.51
MO	%	M/F	7.89	4.56	12.37
EO	%	M/F	2.73	0.70	7.80
BA	%	M/F	0.59	0.22	1.13
NE	x 10 ³ cells/ μ L	M/F	3.59	1.87	7.18
LY	x 10 ³ cells/ μ L	M/F	1.81	1.10	2.73
MO	x 10 ³ cells/ μ L	M/F	0.47	0.29	0.82
EO	x 10 ³ cells/ μ L	M/F	0.17	0.04	0.48
BA	x 10 ³ cells/ μ L	M/F	0.04	0.02	0.08
RET	%	M/F	0.95	0.09	1.81
RET	x 10 ⁶ cells/ μ L	M/F	0.04	0.00	0.08

ABOUT THE UPDATE LABELS

The update labels (located on a separate page) flag you that the information in a manual has been updated, and the new information is located in this addendum. Place the update labels into your GEN•S System Operator's Guide or Reference manual as instructed.

INSTRUCTIONS

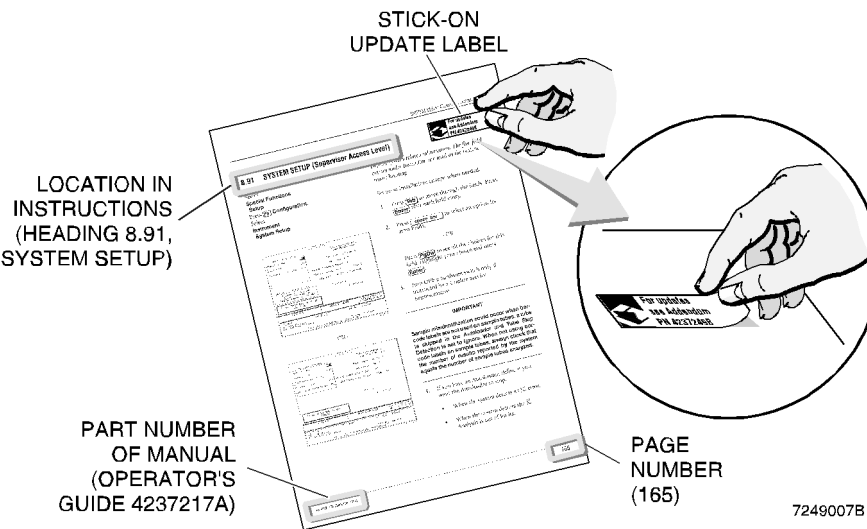


1. Locate a label icon in this addendum and you will find related instructions where to place an update label.
2. Open up the manual to the page number listed in the instructions.
3. Peel off an update label.
4. Place the label on the page near the location mentioned (such as, heading or table number). See the example below.

EXAMPLE



Place an update label in the Operator's Guide on page 165 near heading 8.91, System Setup.



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| ■ Host Transmission
PN 4237306 | Specifications for transmitting to a host computer |
| ■ Reference
PN 4237221 | Use and Function • Installation • Operation Principles • Specifications/Characteristics • Precautions/Hazards • References • Glossary • Index
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The Getting Started booklet and the Host Transmission manual come with your GEN•S System.

The information in the Reference manual, Operator's Guide, Special Procedures and Troubleshooting manual and the SlideMaker Operator's Guide comes from the Online Help System. Each of these hard-copy documents comes with a Master Index.

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